PB89-141071

Guidance for the Reregistration of Pesticide Products Containing Oxydemeton-Methyl as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Sep 87

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB89 141071/AS

4. Title and Subtitle

Guidance for the Reregistration of Pesticide Products Containing Oxydemeton-Methyl as the Active Ingredient

5. Report Date September 1987

6.

7. Author(s) EPA, Office of Pesticide Programs Registration Div.

8. Performing Organization Rept. No. 540/RS-88-134

9. Performing Organization Name and Address

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

oxydemeton-methyl.

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 171

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)

EPA

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

PB89-141071

Pesticides

540/RS-88-134

Guidance for the Reregistration of Pesticide Products Containing OXYDEMETON-METHYL as the Active Ingredient

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires 11/89

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

OXYDEMETON-METHYL
(058702)

AS THE ACTIVE INGREDIENT

Case Number 258

CAS 301-12-2

September 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C.

1.6

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GLOSSORY OF TERMS AND ABBREVIATIONS

ADI:	Acceptable Daily Intake
a.i.:	active ingredient
CAS:	Chemical Abtract Services (number)
CSF:	Confidential Statement of Formula
EPA:	The U.S. Environmental Protection Agency (Agency)
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
LC_{50}:	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).
LD_{50}:	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg)
LEL:	Lowest Effect Level
MPI:	Maximum Permissible Intake
MRID:	Master Record Identification (number) - EPA's system of tracking studies used in support of registration
NPDES:	National Pollution Discharge Elimination System
NOEL:	No Observed Effect Level
OPP:	The Office of Pesticide Programs of the U.S. EPA
OES:	The Office of Endangered Species, U.S. Fish and Wildlife Service
RfD:	Reference Dose

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review, EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request*, focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of a conclusion from available data in its files pertaining to the pesticide active ingredient (ai). However, during the review of these data, the Agency is also looking for potential hazards that may be associated with the end-use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end-use products if necessary to protect man and the environment.

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*The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M Street SW., Washington, DC 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. (See Section IV - Regulatory Position and Rationale.) Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially-trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA section 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA section 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THE STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard.

Common name: Oxydemeton-methyl

Chemical name: S-[2-(Ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate

Other Chemical Names: Demeton-o-methyl; s-2-ethylsulphinylethyl-o,o-dimethyl phosphorothioate; metilmerkaptofosoksiol; o,o-diemthyl-s-[2-(ethylsulfinyl) ethyl]phosphorothioate; demeston-s-methylsulfoxid;

Trade Names: R2170; Metasystemox; Metasystox-R; and Bay 21097

Chemical Class: Organophosphate

Empirical formula: $C_6H_{15}O_4PS_2$

Molecular weight: 246.3

CAS Registry No.: 301-12-2

ENT Registry No.: 24964

Shaughnessy No.: 058702

Physical/chemical properties of pure oxydemeton-methyl, and of the 53.1% FI[a] and 90% unregistered T:

Color: Colorless (P), yellow-brown (T), Yellow to amber (FI)

Physical state: liquid (P, FI)

Odor: Odorless (P), Typical sulfur-containing (T)

Melting Point: <10° C (P), <10° C (T)

Boiling Point: 106° C at 0.013 mbar (P)

Specific Gravity: 1.289 at 20° C (P), 1.03 at 20° C (FI)

Solubility: 10-100 g/100 ml of xylene, cyclohexanone, 2-propanol, and methylene chloride at 20° C (P). Miscible in water at 20° C (P).

Vapor Pressure: 3.8 x 10^{-5} mbar at 20° C (P)

Dissociation Constant: N/A

Octanol/Water Partition Coefficient: 0.18 (P)

pH: N/A

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[a] FI = 53.1% Formulation Intermediate; T = unregistered 90% Technical; P = Pure Active ingredient

B. Use Profile

Oxydemeton-methyl is a broad spectrum systemic organophosphate insecticide/acaricide registered for use to control many insects, primarily aphids, mites and thrips. Registered sites include terrestrial food crops (vegetable, field tree fruit, and nut crops), terrestrial nonfood crops (ornamentals and forest trees), greenhouse nonfood crops (research crops not for consumption), domestic indoor and outdoor, and forestry (trunk injection only). However, the predominant use of oxydemeton-methyl is on vegetables.

Usage statistics indicate that about two-thirds of all the oxydemeton-methyl used in the United States is used in California. Major uses of oxydemeton-methyl in California are on broccoli, cauliflower, and sugar beets. Outside California the major uses include cotton, ornamentals, and alfalfa.

Oxydemeton-methyl is formulated in combination with trichlorfon, methoxychlor, carbaryl, dinocap, dicofol, or folpet. Single ai formulations consist of 0.48 to 4.0 lb/gal EC, 2%, 2.45%, and 13.5% EC and 50% P/T. Oxydemeton-methyl is usually applied by broadcast spray using ground equipment or aircraft, but may also be applied by soil or tree trunk injection.

C. Registration History of Oxydemeton-Methyl

1. Federal Registration Activity

Oxydemeton-methyl was first registered as a 50% technical product, for formulating purposes only, by Mobay Chemical Corporation in 1961. Oxydemeton-methyl is produced in the Federal Republic of Germany by Bayer AG, and in the United States by Mobay Chemical Corporation, Agricultural Chemicals Division. Mobay Chemical Corporation produces an unregistered 90% technical product. There are thirty (30) registrants of products containing oxydemeton-methyl either as a sole active ingredient or in combination with other chemicals. Currently, there are approximately 38 products federally registered; 40 Special Local Need [FIFRA §24(c)] registrations, and seven (7) intrastate registrations.

Five Data Call-In (DCI) Notices have been issued on oxydemeton-methyl. The first notice, dated July 26, 1984, was issued because teratology (rat and rabbit) and reproduction (rat) studies were classified as core-supplementary and needed either additional information or a repeat study. Registrants (basic producers) were requested to either make available to the Agency missing information or submit new studies. Additional information has been received.

The second DCI Notice was issued February 28, 1985 and required submission of reentry data to determine if the 48-hour reentry interval imposed under 40 CFR 170 (3)(b) is adequate. A protocol for gathering these data has been submitted and approved. The reentry data are due in December 1987.

The third DCI Notice, dated April 9, 1986, sent to Mobay and Aceto Chemical Co.(the basic registrants), required exposure data to assess potential exposure to mixers, loaders, and applicators from current registered ornamental (non-injection) uses. This DCI Notice also required submission of data for product chemistry, residue data, wildlife and aquatic organisms, environmental fate, and toxicology. In response, Mobay agreed to conduct all studies with the exception of the exposure studies on the ornamental uses. Instead, Mobay chose to delete the ornamental uses from its registrations. These data are due from January 1987 to June 1990. Subsequently, Aceto's oxydemeton-methyl registrations were suspended for failure to comply with the DCI.

Since Mobay declined to provide exposure data on the ornamental uses, a fourth DCI Notice dated September 23, 1986, was sent to the end-use registrants, requesting that they provide the exposure data, or delete the ornamental use from their labeling. No end-use registrant agreed to generate the required exposure data. All end-use registrants have either requested voluntary cancellation of their registrations for the non-injection ornamental uses or have been suspended for failure to respond to the DCI Notice.

The fifth DCI Notice dated June 1987, was sent to all registrants with products containing oxydemeton-methyl. Two animal studies concerning toxicity to the male reproductive system were required, one using short-term dosing and the other using long-term dosing. The short-term dosing study is due by October 31, 1988. If the ongoing study being conducted by Mobay for the California Department of Food and Agriculture is submitted to satisfy the long-term data requirement, that study must be submitted by December 31, 1987. If a new study is undertaken to satisfy this requirement, the new study must be submitted by October 31, 1988.

2. California Registration Activity

A two-generation reproduction study was submitted to the Agency in December 1985. In Spring 1986, the California Department of Food and Agriculture (CDFA) notified EPA of its concerns and that it was considering taking further regulatory action on oxydemeton-methyl. At that time, EPA had questions regarding that reproduction study, and decided not to take action at that time. Subsequently, the Agency's questions were resolved and the study was upgraded to Core Minimum Data in December 1986.

On December 16, 1986, CDFA imposed a number of restrictions on the agricultural uses of oxydemeton-methyl, and on December 23, 1986, CDFA suspended all home use products. Restrictions imposed by CDFA for the agricultural uses included: (a) use only pursuant to a use permit; (b) use only by licensed pest control operators; (c) closed systems; (d) full body protection; (e) enclosed vehicles required for flaggers (or full body protection); (f) required distribution of an information document to users; (g) requirements for cleaning (or discarding) protective equipment.

In addition, CDFA required Mobay to develop four additional studies. These studies (and dates they are due to be submitted to CDFA) are: (i) male rat reproductive system toxicity study/December 1987; (ii) a repeat two-generation rat reproduction study/Fall 1988; (iii) a comparison between oral and dermal cholinesterase dose responses/December 1987; and (iv) a monkey dermal absorption study/September 1987.

III. AGENCY ASSESSMENT

A. Science Findings

1. Toxicology

The following is a summary of scientific findings based on the available toxicity data on oxydemeton-methyl.

Acute Effects

Sufficient data are available to classify technical oxydemeton-methyl (ODM) as Toxicity Category I due to its dermal toxicity, with an acute dermal toxicity of 152 mg/kg and 112 mg/kg for male and female rats, respectively. ODM is moderately toxic (Toxicity Category II) by the inhalation route, 1.5mg/L and 0.51mg/L for rats and mice, respectively. ODM produces mild but reversible irritation of the conjunctivae in rabbits (Toxicity Category III) and is not considered to be a dermal irritant (Toxicity Category IV). Available data, inadequate for regulatory purposes, suggest that ODM has moderate acute oral toxicity (Toxicity Category II). A new acute oral toxicity study is required. No dermal sensitization study is available, and is therefore required.

The acute delayed neurotoxicity data could not be evaluated due to incomplete reporting and discrepancies in the reported results. However, evidence of positive effect has been demonstrated in the sciatic and tibial nerves of hens treated with oxydemeton-methyl. To confirm these findings the Agency is requiring additional neurotoxicity data.

Subchronic Effects

In a subchronic oral study, groups of 30 rats/sex/dose each were given oxydemeton-methyl in the diet at 0, 1, 10, or 100 ppm. Administration of 10 ppm in the diet resulted in a significant decrease in the mean corpuscular volume (females) and a significant increased incidence of histopathologic changes in the lungs of males. At the 100 ppm dosage level, significant alterations in hematology, clinical chemistry parameters, absolute and relative organ weights, as well as histopathologic changes in the lungs of both males and females were found. Plasma, erythrocyte, and brain cholinesterase activities were significantly decreased at the 10 and 100 ppm dosage levels. The submitted data are not sufficient to assess the subchronic toxicity of oxydemeton-methyl. The Agency is requiring the submission of additional data.

The subchronic inhalation study is acceptable and demonstrates that repeated inhalation exposure for 30 days to technical oxydemeton-methyl results in a systemic NOEL of equal to or less than 0.176 mg/L/day for both rats and mice.

Subchronic Dermal (90-day) data are not needed since the currently registered uses for oxydemeton-methyl are not expected to result in repeated human contact for extended periods (i.e., purposeful dermal application to, or prolonged exposure of, human skin).

Oxydemeton-methyl is an organophosphate and as such has the potential to produce neurotoxicity. An acute delayed neurotoxicity study in hens will be required.

The submitted subchronic (21-day) dermal study in rabbits is inadequate for regulatory purposes (only 3 rabbits/dose). A new study is required.

Chronic Effects

A 1-year dog study conducted with dietary concentrations of 0, 0.0125, 0.125, and 1.25 mg/kg/day with 50% concentrate of technical material, rather than technical grade active ingredient, showed inhibition of red blood cell (RBC) and brain cholinesterase at the mid-dose. However, the study is not acceptable due to inadequate histopathology and physical examinations, and the use of the 50% concentrate instead of the technical material. A new study with technical oxydemeton-methyl is required.

The chronic feeding study in rats is not reported in a manner which permits a valid assessment of chronic toxicity. Additional data and/or clarification by the data submitter are required. A new study will be required if the deficiencies are not adequately addressed.

Oncogenicity

The submitted oncogenicity data are inadequate and preclude an assessment of the oncogenic potential of oxydemeton-methyl.

The mouse oncogenicity study submitted to the Agency has numerous deficiencies, tabulation errors, and histopathologic inadequacies. A complete revision of the study report is requested. A new study will be required if these issues are not satisfactorily resolved.

The rat oncogenicity study is not reported in an acceptable manner which permits a valid assessment of the chronic toxicity or oncogenic potential. The Agency requests a revision of the study report, in which all necropsy findings, for terminally sacrificed animals should be tabulated separately from animals which died during the study or sacrificed _in extremis_. A new study will be required if these issues are not satisfactorily resolved.

Teratogenicity

Sufficient data are available to satisfy the regulatory requirements in two species.

Groups of at least 45 pregnant CD rats were each gavaged with technical oxydemeton-methyl at 0, 0.5, 1.5, or 4.5 mg/kg/day during the period of organogenesis (days 6-15 of gestation). On day 16 of gestation, 5 females in each group were sacrificed for cholinesterase determination. On day 20 of gestation, at least 20 pregnant dams in each group were sacrificed for routine teratogenic examinations. The rest of the animals were allowed to deliver and raise their offspring up to postnatal day 21 of lactation for behavioral testing. From the data presented in the conventional teratology and the postnatal segments of this investigation, the maternal no-observed-effect-level (NOEL) was 1.5 mg/kg/day with the maternal lowest-effect-level (LEL) established at 4.5 mg/kg/day as evidenced by reduced body weight gains and food consumption. The maternal cholinesterase NOEL was equal to or less than 0.5 mg/kg/day (lowest dose tested). The developmental toxicity NOEL was determined at 1.5 mg/kg/day. No evidence of frank teratogenic effects was demonstrated.

Oxydemeton-methyl (50% concentrate) was administered to groups of 17 rabbits each from days 7 to 19 of gestation. The doses used were 0.05, 0.2, and 0.8 mg/kg/day (expressed as ai). All does were sacrificed on day 28 of gestation and routine teratology procedures were performed. Significant inhibition of brain and erythrocyte cholinesterase activity was observed at the 0.8 mg/kg dosage level. The maternal NOEL was 0.2 mg/kg/day with the maternal LEL at 0.8 mg/kg/day. No major frank teratogenic effects were observed but very minor evidence of developmental toxicity in the form of incomplete ossification of the metacarpals was noted in the treated groups. The developmental toxicity LEL was determined to be 0.05 mg/kg/day (lowest dose tested).

Reproduction

The review of data, primarily from two studies, has raised substantial concerns regarding the potential for reproductive effects resulting from exposure to oxydemeton-methyl. The data include a two-generation rat reproduction study and interim progress reports of an on-going male rat reproductive toxicity study. The observed effects include decreases in the fertility index, testicular weight, litter size, pup weight, and pup survivability. Also, histopathologic changes in the epididymis and alterations in sperm morphology and motility have been found.

In the two-generation reproduction study, rats were fed 0, 1, 10, or 50 ppm of oxydemeton-methyl in the diet. At the 50 ppm dosage level, decreases were noted in parental body weights, fertility index, litter size, parental testis weight, and pup weight, as well as increased pup mortality. Further, vacuolization of the epithelial cells in the corpus area of the epididymis was noted in 10/10 males examined. At the 10 ppm dosage level, decreased parental body weights and testis weight, and increased pup mortality were demonstrated. Vacuolization of the epithelial cells in the corpus area of the epididymis was observed in 1/10 males examined. At the 1 ppm dosage level, no effects on fertility, pup body weight, and pup survivability were found. A significant decrease in absolute testis weight was noted in F_1 parental animals. The biological significance of that finding is not known because the testis weight in this group was higher than that of the historical control range and approximated that of the F_0 parental control group. Histopathologic changes of the epididymis were not found.

Based upon these findings, a reproductive NOEL was established at 1 ppm, and the lowest-observed-effect-level (LOEL) was established at 10 ppm. However, after 2 days in the diet, approximately 20% of the oxydemeton-methyl degraded; therefore, the NOEL and LOEL may be somewhat lower.

Three of four progress reports (exposure to oxydemeton-methyl for 2 months, 4 months, and 6 months) on the male reproductive system toxicity study (male fertility study) in rats exposed to 3, 9, and 50 ppm of oxydemeton-methyl in the diet, have been submitted and reviewed by the Agency.

In the 2-month interim report, vacuolization of the epididymis was reported in 10/10 males exposed to 50 ppm of oxydemeton-methyl in the diet. After 4 months of exposure, vacuolization of the epididymis was still evident in all animals in the 50 ppm group with a higher grading of severity than at 2 months. Further, 5/9 animals in the 9 ppm group were described with minimal or slight vacuolization in the body of the epididymis after being treated for 4 months. Some animals in the 50 ppm dose group were put on the control diet for 2 weeks after being treated for 3.5 months. In that recovery group, vacuolization was still present in all animals; however, the investigators stated that "the severity of the vacuolization was decreased in the mid and distal portion of the body of the epididymis". After being exposed to oxydemeton-methyl in the diet for 2 months, male rats in all dosage groups showed significant increases in the percent of sperm with bent flagella. Significant differences were not found after 4 months but a higher incidence was still evident in the 3 ppm, 9 ppm, and recovery group.

Vacuolization of the corpus epididymis was previously observed in the two-generation rat reproduction study affecting 1/10 and 10/10 animals fed with 10 and 50 ppm, respectively. The same finding was observed in the male reproductive study at the 2-month interval and affecting 10/10 animals in the 50 ppm group. After 4 months of exposure, there was an increase in the severity of the vacuolization in all 50 ppm males. Further, vacuolization was also observed in 5/9 males in the 9 ppm group. These findings confirmed that vacuolization of the epididymis was compound-related and the severity of the lesion was a function of the length of exposure. In the recovery group, vacuolization was still evident in all animals. The latter suggests that, at least at the 50 ppm dosage level, the epididymal lesion induced by oxydemeton-methyl did not reverse completely after 2 weeks of recovery.

The 6-month progress report also confirmed that vacuolization of the corpus epididymis was treatment-related. The severity of the lesion may be a function of the length of exposure, as evidenced by the presence of unilateral or bilateral fine vacuolization in the dpididymal head observed in 7 of 9 animals in the 50 ppm dose group. One animal in the 9 ppm dose group had epididymal lision after 6 months of exposure to ODM, a finding similar to that found in the 50 ppm dose group. The 6-month recovery group (animals treated with ODM for 4 months at 50 ppm, followed by 2 months on the control diet) still exhibited lesions in the proximal epididymes. Thus, complete reversibility of the epididymal lesions has not been demonstrated in any of the recovery groups (4 and 4-month interim reports).

Mutagenicity

To assess the mutagenic potential of a chemical, the Agency requires a battery of tests to address three categories of possible genetic effects: 1) gene mutation; 2) structural chromosomal aberrations; and 3) other mutagenic mechanisms, including numerical chromosomal aberrations and DNA damage and repair. Oxydemeton-methyl data indicate that it produces a dose dependent increase in mutation frequency in Salmonella in the presence and absence of metabolic activation.

In the mouse lymphoma forward mutation assay, a concentration-dependent increase in mutation frequency is also observed in both the presence and absence of metabolic activation. The effects of oxydemeton-methyl on chromosomal aberration and DNA damage are inconclusive. Therefore, a relationship between mutagenicity and adverse reproductive effects cannot be ruled out. Additional testing is required.

Metabolism

Acceptable data relative to the metabolic pathway of oxydemeton-methyl are not available. A metabolism study is required.

2. Ecological Effects

Avian Species

The avian acute oral studies with 50% ai oxydemeton-methyl indicate that the acute toxicity ranges from moderately toxic to highly toxic, depending on the species of bird tested. The acute toxicity values range from 14 mg/kg (rock dove) to 47.6 mg/kg (California quail) for the highly toxic range and from 53.9 mg/kg (mallard) to 120 mg/kg (Chuka) for the moderately toxic range. Likewise, 8-day dietary studies demonstrate that there is a wide range of toxicity from practically nontoxic (>5000 ppm for mallards) to highly toxic (434 ppm for bobwhite quail). Additional data are not required.

No acceptable avian reproduction studies are available. Data are required to support uses of oxydemeton-methyl on crops with multiple applications such as cotton, alfalfa, grapes and sugar beets.

Avian terrestrial field studies are not required. A comparison of the acute toxicity values with estimated pesticide residues on food items indicate that birds are not expected to be exposed to lethal concentrations of oxydemeton-methyl in the field at application rates up to 0.75 lb ai/A (the highest rate currently registered).

Aquatic Organisms

The acute toxicity tests with freshwater invertebrates indicate that oxydemeton-methyl is very highly toxic to daphnids, moderately toxic to isopods, and moderately to highly toxic to amphipods. The acute toxicity values are 3.3 ppb for daphnids, 1400 ppb for isopods, and 190 to 1000 ppb for amphipods. However, none of the available studies satisfy the requirement for an acute toxicity study for freshwater invertebrates since older specimens were used in the tests. A new study is required.

The acute fish studies indicate that oxydemeton-methyl is moderately to highly toxic to coldwater fish and slightly to moderately toxic to warmwater fish. The 96-hour acute toxicity values ranged from 0.73 ppm to 6.4 ppm for rainbow trout and from 1.22 ppm to 31.5 ppm for several species of warmwater fish. Additional data are not required.

Evaluation of tests on a 25% ai oxydemeton-methyl concentrate product, indicates this formulation is moderately toxic to estuarine crustaceans. The 96-hour acute toxicity value for pink shrimp (Penaeus duorarum) was 1.2 (0.9-1.8) ppm, and the 96-hour acute toxicity value for fiddler crab was 8.6 (6.6-11) ppm. Based on currently registered uses, oxydemeton-methyl is not expected to enter estuarine environments in significant concentrations. Therefore, the Agency is not requiring additional acute toxicity testing on estuarine organisms.

Nontarget Insects

Studies indicate that oxydemeton-methyl is moderately to highly toxic to honey bees exposed to direct application. However, toxicity of foliar residues appears to be short lived. Toxicity to honey bee larvae is highly variable depending upon larval development at the time of exposure. It is unlikely that these nontarget insects would be affected by application of oxydemeton-methyl made in accordance with label directions.

Endangered Species Considerations

Although the toxicity data indicate that oxydemeton-methyl is highly toxic to bobwhite quail, *Daphnia magna*, and rainbow trout, its toxicity to other species of birds and aquatic organisms is considerably lower.

The Attwater's greater prairie chicken is considered to be in jeopardy from the use of highly toxic pesticides on cotton. However, use of oxydemeton-methyl does not appear to present a problem. This species principally consumes insects such as grasshoppers and some plant foods, such as seeds. A single application of oxydemeton-methyl at the rate of 0.5 lb ai/A will produce residues on these food items at levels below the endangered species risk criteria [1/10 the LC_{50} value (the bobwhite quail serve as the model for this endangered bird)]. The Aleutian Canada goose is considered to be in jeopardy from the use of highly toxic pesticides on alfalfa. However, the use of oxydemeton-methyl is unlikely to jeopardize this species since the acute toxicity value of the mallard duck, which is the model for this endangered waterfowl, is greater than 5000 ppm or practically nontoxic. The data on risks to aquatic organisms demonstrate that the maximum concentration in water (27.6 ppb) is less than the risk criterion for endangered fish species (1/20 the LC_{50} value).

3. Environmental Fate

With the exception of a hydrolysis study, available data reviewed by the Agency are not sufficient to fulfill data requirements. Therefore, the environmental fate of oxydemeton-methyl cannot be fully assessed. Available data are not adequate to fully assess leaching potential (e.g., field dissipation). Oxydemeton-methyl and its degradation products are soluble in water. The Agency cannot conclusively determine the potential for ground water contamination at this time. Photodegradation on soil does not appear to be a significant route of degradation for oxydemeton-methyl. Under aerobic conditions, as indicated by preliminary studies, oxydemeton-methyl breaks down in soils of different textures to dimethyl phosphate, 2-sulfonic diethyl sulfoxide, 2 sulfonic diethyl sulfone, and oxydemeton-methyl sulfone.

Reentry

Reentry data are not available to assess the potential exposure to humans entering areas treated with oxydemeton-methyl. The 48-hour reentry interval set under 40 CFR 170 for all agricultural uses of oxydemeton-methyl is being retained until adequate exposure data have been submitted and evaluated.

B. SUMMARY OF DATA GAPS:

Toxicology

- Acute Oral
- Dermal Sensitization (Guinea pig)
- Acute Delayed Neurotoxicity (Hens)
- Subchronic Oral (Rat, non-rodent)
  (Not required if chronic data are acceptable)
- Subchronic Dermal (21-Day; Rabbit)
- Subchronic Neurotoxicity
  (Required if the acute delayed neurotoxicity is positive)
- Chronic Toxicity (Rat, dog)
- Oncogenicity (Rat, mouse)
- Mutagenicity Tests (Chromosomal and DNA)
- Metabolism
- Male Short Term Exposure Study
- Male Reproductive System Toxicity Study

Environmental Fate/Exposure

- Photodegradation
  - In water
  - In soil
  - In air (conditional)
- Metabolism - Lab
  - Aerobic Soil
  - Anaerobic Soil
- Mobility
  - Leaching and Adsorption/Desorption
  - Laboratory Volatility
  - Field Volatility (conditional)
- Terrestrial Field Dissipation
  - Field Dissipation - Soil
  - Long-term Field Dissipation (conditional)
  - Confined Rotational Crop
  - Field Rotational Crop (conditional)
- Spray Drift Studies
  - Droplet Size Spectrum
  - Drift Field Evaluation
- Reentry
  - Foliar Dissipation
  - Soil Dissipation

Ecological Effects

- Avian Reproduction
- Aquatic Invertebrate Acute Toxicity
- Fish Early Life Stage and Aquatic Invertebrate Life Cycle
- Aquatic Organism Accumulation

Residue Chemistry/Product Chemistry

- Product Chemistry
- Plant and Animal Metabolism
- Storage Stability
- Magnitude of Residue Studies (Plant)

C. HEALTH RISK ASSESSMENT

1. Reproductive Effects

The Agency reviewed data from two studies that raised substantial concerns regarding potential reproductive effects resulting from exposure to oxydemeton-methyl. The data, submitted by Mobay Chemical Corporation, include a two-generation rat reproduction study and interim progress reports of an on-going male rat reproductive system toxicity study. Oxydemeton-methyl has the potential to adversely affect reproduction, as shown by rats with histopathologic changes in the epididymis, alterations in sperm morphology and motility, and decreases in the fertility index, testicular weight, litter size, pup weight, and pup survivability. (See section III.A.1 for further discussion of these studies.) The no-observed-effect-level (NOEL) for reproductive effects has been established at 1 ppm (approximately 0.05 mg/kg/day) from the two-generation rat reproduction study.

2. Toxicity and Poisoning Incidents

ODM is a potent cholinesterase inhibitor. The effects of oxydemeton-methyl on human cholinesterase activity were investigated by the University of Kansas. Human volunteers were exposed to either a single oral dose or repeated oral doses for 60 days. The dosage levels for the single oral dose ranged from 0.0125 to 1.5 mg/kg/day (one volunteer per dose level), and the dosage levels for repeated exposure were from 0.05 to 0.4 mg/kg/day (one volunteer per dose level).

Single oral doses of oxydemeton-methyl up to and including 0.5 mg/kg/day did not produce any change in either the plasma or red blood cell (RBC) cholinesterase activity. At 1.0 and 1.5 mg/kg/day, plasma and RCB cholinesterase activities were decreased. Oral administration of 0.05 mg/kg/day for up to 60 days were without noticeable effects on human blood cholinesterase activities. Inhibition of plasma and RBC cholinesterase activities were found in individuals administered any dose higher than 0.05 mg/kg/day. In humans, the cholinesterase NOELs after single and repeated oral administration were established at 0.5 mg/kg/day and 0.05 mg/kg/day, respectively.

The Pesticide Incident Monitoring System (PIMS) files show 67 incident reports involving oxydemeton-methyl from 1966 to August 1978, the period for which records are available. Fifteen reports cite the involvement of oxydemeton-methyl alone. Fifty-two reports cite oxydemeton-methyl in combination with other pesticides.

Based on data obtained from California (the only State which enforces mandatory reporting of occupational pesticide incidents), 14 illnesses involving oxydemeton-methyl were reported for the period 1981 through 1985. During that time, physicians treated an average of 1.8 oxydemeton-methyl poisonings per year, and an additional one case per year was reported from either skin or eye injury. Of these 14 illnesses, 7 occurred to applicators, 3 were from exposure to residues or drift, 2 occurred to mixer/loaders, and 2 were from "other causes". In addition, between 1981 and 1985 four people were reported hospitalized for occupational oxydemeton-methyl poisoning for a total of 10 days, and 11 workers were off work for a total of 54 days. No accidental deaths were reported in California from 1965 to 1977 or from 1981 to 1985 when all accidental deaths from pesticides were required to be reported.

3. Worker Exposure

The Agency has received ODM-specific exposure estimates from the California Department of Food and Agriculture. In addition, the Agency estimated exposure for individuals using various application equipment, based on surrogate data.

ODM-specific Data. The California Department of Food and Agriculture (CDFA) provided the Agency with exposure estimates, specific for use of oxydemeton-methyl in California on cole crops (broccoli, cauliflower, cabbage, and Brussels sprouts). CDFA has conducted an exposure study to determine the effectiveness of the measures taken independently by California to regulate oxydementon-methyl [requiring the use of full body protection ("rainsuits") and closed mixing/loading systems]. According to CDFA, these measures may result in dermal exposure of 1 to 2 mg per tractor driver per seven-hour shift, for treatment to cole crops. These dermal exposure estimates may either understate or overstate the expected exposure in areas other than California.

These estimates may understate exposure because (1) the climate in the oxydemeton-methyl use areas of California is conducive to such protective measures and they are, therefore, more likely to be used, and (2) the comprehensive surveillance program in California induces people to more fully comply with the requirements than may result in other areas of the country. On the other hand, most users are probably exposed to oxydemeton-methyl a few days per year. However, CDFA cites that professional applicators in California may perform repeated applications of oxydemeton-methyl. Therefore, applicators in California may have very frequent exposures to ODM, resulting in a greater exposure estimate than for applicators in other areas of the country.

Surrogate Data. The Agency estimated the exposure to individuals using oxydemeton-methyl with various application equipment. These estimates were based on surrogate exposure data where "normal" work attire was worn (short- or long-sleeved shirt and long pants) and the only protective clothes/equipment used were protective gloves during mixing and loading. Oxydemeton-methyl labels do not presently state specific protective clothing or equipment to be used. Currently, the labels only require "appropriate" protective clothing for early reentry.

Using that surrogate exposure data, daily dermal exposure is estimated to be highest (2.6 mg/kg/day) for combined mixing, loading, and applying oxydemeton-methyl by airblast to citrus. It was assumed that oxydemeton-methyl is applied to citrus for 8.5 hours/day, one application/year over 2 consecutive days.

Ground boom applications to representative vegetable and field crops and grapes result in generally the same estimated daily exposures, about 0.5 to 2.0 mg/kg/day, when the surrogate exposure data are used. For these calculations, it was assumed that oxydemeton-methyl is applied to:

- broccoli and cauliflower for 6.7 hours/day, one day/application, usually two applications/yr.;
- cabbage for 3.7 hours/day, one application/yr. for one day outside CA (average of 2 applications/ yr. in CA);
- sugar beets for 8 hours/day, one day per application, usually two applications/yr.; and
- cotton for 6.6 hours/day, four days/application, usually two applications/yr. (i.e., 8 days/yr.).

For those crops where an average of two applications are made per year, the label permits these applications to occur as necessary or in some cases the intervals are specified as 10 to 14 days apart; however, these applications may occur at greater intervals.

Exposure estimates for pilots from aerial application to some of these same representative crops are lower, about 0.02 to 0.09 mg/kg/day (assuming approximately 2 to 2.3 hours/day, two applications/yr.).

The ornamental uses may result in exposure estimates from about 0.04 to 0.6 mg/kg/day (commercial: 1 hour/day, 2 applications/ yr., 1 day/application; domestic: 10 to 30 min./day, six applications/yr.).

4. Dietary Exposure

Workers may also be exposed to residues of oxydemeton-methyl through the diet. Refer to the discussion in the Dietary Exposure section of Part D. Tolerance Reassessment of this chapter.

5. Mixer/Loader and Applicator Risks

Margins-of-safety (MOSs) were calculated for worker exposure using both the Agency's surrogate exposure estimates and the oxydemeton-methyl exposure estimates given to the Agency by CDFA. All MOSs resulting from both the surrogate exposure data and the oxydemeton-methyl exposure data assume a reproductive effects NOEL = 0.05 mg/kg/day, a 70 kg person, and 50% dermal absorption. (Dermal absorption data indicate that absorption of oxydemeton-methyl is approximately 50%.)

The surrogate exposure data were used to calculate MOSs two different ways (see Table 1): 1) daily exposure was compared directly to the NOEL observed in the two-generation rat reproduction study and 2) exposure was averaged over a year and then compared to the NOEL. The average daily exposure over a year was calculated by multiplying daily exposure by the number of days per year of use and then dividing that number by 365. (This number was then compared to the NOEL from the two-generation rat reproduction study.) The MOSs given in Table 1 might increase, roughly 10-fold, if maximum, full body protective clothing and/or equipment is used.

Two methods for calculating MOSs were used because the two-generation rat reproduction study (from which the NOEL = 0.05 mg/kg/day was derived) used what could be considered a chronic dosing regimen, and oxydemeton-methyl is applied only a few times per year in the majority of cases. Therefore, most users of oxydemeton-methyl have acute, not chronic, exposures. As a result, the MOSs given in Tables 1 and 2 for daily exposures (which result when the daily exposure is compared directly to the NOEL) may overestimate risks for acute exposures. However, the MOSs which result when exposure is averaged over a year do not necessarily represent the MOSs that might result from actual studies of short-term exposure. Both sets of MOSs are presented here in order to give a range of risk estimates in an attempt to bracket the uncertainty involved in comparing short-term exposures to results of longer term studies. The Agency recognizes that neither set of MOSs may actually represent the risks being encountered by mixers, loaders, and applicators.

At this time, the Agency does not have appropriate data to characterize the risks associated with short-term exposure. The Agency has issued a Data Call-In (DCI) Notice, dated June 30, 1987, requiring a study to be generated and submitted to the Agency which is designed to evaluate the toxic effects resulting from short-term exposure to oxydemeton-methyl. That study is required to be submitted to the Agency by October, 1988.

Another concern is that frequent, multiple exposures to oxydemeton-methyl do occur to some mixers/loaders/applicators as has been reported to occur in California. However, without more definitive information on the length of time each day and the number of days per year that mixers/loaders/applicators are exposed, the Agency cannot determine whether this exposure is sub-acute or chronic. Assuming it is chronic, the MOSs given in the first column (daily exposure) of Table 1 and those shown in Table 2 may reflect the risks posed to these applicators. The Agency is seeking better information on these exposure patterns in order to better characterize the risks to this group of workers.

Reversibility of effects on the male reproductive system depends on whether the affected cell type(s) are replaceable. Effects on spermatogenesis or epididymal function may be reversible, but damage to spermatogonial stem cells or Sertoli cells may prolong or preclude recovery. Also, with a mutagenic agent, a paternally-mediated effect on offspring is possible. Demonstration of full reversibility should not be a factor with longer-term exposures or with intermittent exposures when the interval between exposures is insufficient for full recovery.

The question of whether any adverse effects to the male reproductive system are reversible may be answered when the completed male reproductive system toxicity study (male fertility study) is submitted. That study is also required through the June 1987 DCI Notice, and it is due to be submitted to the Agency by either December 31, 1987 or October 31, 1988. (The male reproductive system toxicity study was already being conducted by Mobay for CDFA when the Agency required a comparable study in its June 1987 DCI Notice. If that on-going study is used to fulfill the requirement, the final report must be submitted to the Agency by December 31, 1987. If a new study is undertaken, the final report must be submitted to the Agency by October 31, 1988.)

TABLE 1

WORKER DERMAL EXPOSURE TO ODM AND MARGIN-OF-SAFETY (MOS)[1]/ USING BOTH DAILY SURROGATE EXPOSURE ESTIMATES AND AVERAGING SURROGATE EXPOSURE ESTIMATES OVER A YEAR

Method of Application	Crop	Daily Exposure[2]/ (mg/kg/day)	MOS[3]/	Ave. Exposure[2]/ (mg/kg/day)	MOS[4]/
Airblast - Mixer/Loader	Citrus	0.10	<1		
- Applicator		2.5	<1		
- Combined		2.6	<1	.014	8
Ground Boom - Mixer/Loader	Broccoli/	0.59 - 0.83	<1		
Applicator	Cauliflower	0.27 - 0.35	<1		
Combined		0.86 - 1.2	<1	.005 - .007	12 - 18
Ground Boom - Mixer/Loader	Cabbage	0.44	<1		
Applicator		0.19	<1		
Combined		0.63	<1	.002	45
Ground Boom - Mixer/Loader	Sugar Beets	0.71 - 1.4	<1		
Applicator		0.32 - 0.63	<1		
Combined		1.0 - 2.0	<1	.005 - .010	8 - 18
Ground Boom - Mixer/Loader	Grapes	0.29 - 0.43	<1		
Applicator		0.17 - 0.25	<1		
Combined		0.46 - 0.68	<1	.002 - .004	23 - 45
Ground Boom - Mixer/Loader	Cotton	0.65 - 0.87	<1		
Applicator		0.26 - 0.35	<1		
Combined		0.91 - 1.2	<1	.020 - .027	4 - 5
Aerial - Mixer/Loader	Broccoli	0.029 - 0.038	<3	.00003 - .0005[5]/	179 - 2975[5]/
- Pilot		0.008 - 0.011	<10		
Aerial - Mixer/Loader	Cauliflower	0.017 - 0.023	<5		
- Pilot		0.005 - 0.007	<15		
Aerial - Mixer/Loader	Cotton	0.063 - 0.084	<2		
- Pilot		0.010 - 0.013	<10		
Hand-Held Sprayers - Domestic/Commercial	Ornamentals	0.04 - 0.56	<1	.001 - .003	30 - 89

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[1]/ All MOSs reflect the NOEL = 0.05 mg/kg/day for reproductive effects and a dermal absorption rate of approximately 50%. (These MOSs might increase, roughly 10-fold, if maximum, full body protective clothing and/or equipment could be used.)

[2]/ All surrogate exposure estimates assume the use of protective gloves only (normal work attire) and, approximately, a 70 kg body weight.

[3]/ These MOSs were calculated by comparing the exposure from a single day to the NOEL.

[4]/ These MOSs were calculated by comparing the average daily exposure over a year to the NOEL.

[5]/ Daily exposures from aerial applications to broccoli, cauliflower, and cotton were combined and averaged over a year, and that number was compared to the NOEL to give the resulting MOSs.

TABLE 2

WORKER DERMAL EXPOSURE TO ODM AND MARGIN-OF-SAFETY (MOS)[1] USING ODM-SPECIFIC EXPOSURE ESTIMATES FROM CALIFORNIA FOR APPLICATION TO COLE CROPS

Method of Application	Crop	Daily Exposure[2] mg/kg/day	MOS[3]
Ground Boom - Mixer/Loader Applicator	Cole crops	0.014 to .028	4-8

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[1] MOSs reflect the NOEL = 0.05 mg/kg/day for reproductive effects and a dermal absorption rate of 50%.

[2] Assuming CDFA's dermal exposure estimate of 1 to 2 mg/tractor driver/seven-hour shift, resulting from those restrictions which are currently required by California (maximum, full body protection, including closed loading systems), and a 70 kg body weight, daily exposure would be 0.014 to 0.028 mg/kg/day.

[3] MOSs were calculated by comparing the exposure from a single day to the NOEL.

D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of oxydemeton-methyl expressed in terms of combined residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites on various raw agricultural commodities (40 CFR 180.330)

Commodity	U.S	Canadian 1/	Mexican	Codex 2/
Alfalfa, chaff, or seed	11.0	-	-	-
Alfalfa, green	5.0	-	-	-
Alfalfa, hay for seed	11.0	-	-	-
Apples	1.0	-	-	-
Apricots	0.5	-	-	-
Beans, lima	0.5	-	-	-
Beans, lima, forage	2.0	-	-	-
Beans, snap	0.5	-	-	-
Beans, snap, forage	2.0	-	-	-
Beets, sugar	0.3	-	-	-
Beets, sugar, tops	0.5	-	-	-
Blackberries	2.0	-	-	-
Broccoli	1.0	-	-	-
Brussels sprouts	1.0	-	-	-
Cabbage	1.0	-	-	-
Cattle, fat	0.01	-	-	-
Cattle, mbyp	0.01	-	-	-
Cattle, meat	0.01	-	-	-
Cauliflower	1.0	-	-	-
Clover, chaff, for seed	11.0	-	-	-
Clover, green	5.0	-	-	-
Clover, hay, for seed	11.0	-	-	-
Corn, fodder	3.0	-	-	-
Corn, forage	3.0	-	-	-
Corn, fresh (inc sweet K + CWHR)	0.5	-	-	-
Corn, grain	0.5	-	-	-
Cottonseed	0.1	-	-	-

1/ There are Canadian negligible residue (0.1 ppm) tolerances for the following crops having U.S.-tolerances: beans, caneberries, cole crops, corn, cucumbers, melons, peas, potatoes, pumpkins, squash, strawberries, sugar beets, and turnips.

2/ Codex considers oxydemeton-methyl to be a metabolite of demeton-S-methyl and therefore it is indirectly covered under Codex MRLs as a result of the use of demeton-S-methyl (not oxydemeton-methyl) on a number of crops.

Commodity	U.S	Canadian	Mexican	Codex
Cucumbers	1.0	-	-	-
Eggplant	1.0	-	-	-
Filberts	0.05	-	-	-
Goats, fat	0.01	-	-	-
Goats, mbyp	0.01	-	-	-
Goats, meat	0.01	-	-	-
Grapefruit	1.0	-	-	-
Grapes	0.1	-	-	-
Hogs, fat	0.01	-	-	-
Hogs, mbyp	0.01	-	-	-
Hogs, meat	0.01	-	-	-
Horses, fat	0.01	-	-	-
Horses, mbyp	0.01	-	-	-
Horses, meat	0.01	-	-	-
Lemons	1.0	-	-	-
Lettuce, head	2.0	-	-	-
Melons	0.3	-	-	-
Milk	0.01	-	-	-
Mint, hay	12.5	-	-	-
Onions, dry bulb	0.05	-	-	-
Oranges	1.0	-	-	-
Pears	0.3	-	-	-
Peas	0.3	-	-	-
Peas, forage	2.0	-	-	-
Peas, hay	8.0	-	-	-
Peppers	0.75	-	-	-
Plums (fresh prunes)	1.0	-	-	-
Potatoes	0.1	-	-	-
Pumpkins	0.3	-	-	-
Raspberries	2.0	-	-	-
Safflower	1.0	-	-	-
Sheep, fat	0.01	-	-	-
Sheep, mbyp	0.01	-	-	-
Sheep, meat	0.01	-	-	-
Sorghum, forage	2.0	-	-	-
Sorghum, grain	0.75	-	-	-
Squash, summer	1.0	-	-	-
Squash, winter	0.3	-	-	-
Strawberries	2.0	-	-	-
Turnips	0.3	-	-	-
Turnips, tops	2.0	-	-	-
Walnuts	0.3	-	-	-

A feed additive tolerance of 2.0 ppm is established for the combined residues of oxydemeton-methyl and its cholinesterase inhibiting metabolites in the milled fractions of sorghum (except flour) for animal feed when present therein as a result of application to growing sorghum. (21 CFR 561.234)

Residue Data

The metabolism of oxydemeton-methyl (S-[2-(ethylsulfonyl)ethyl]O,O-dimethyl phosphorothioate) in plants is not adequately understood. Because of the structural similarity between disulfoton, demeton, and oxydemeton-methyl, it is possible that certain metabolites of oxydemeton-methyl will be common to those of disulfoton and/or demeton. However, in the absence of adequate data delineating the nature of the residue of oxydemeton-methyl in plants, no comparisons with demeton or disulfoton plant metabolism can be made at this time. Presently, oxydemeton-methyl and its cholinesterase-inhibiting metabolites are the residues of concern in plants.

The metabolism of oxydemeton-methyl in ruminants and poultry is not adequately understood. The only available *in vivo* ruminant metabolism study did not indicate what percentages of the total radioactivity in tissues and milk were present in the extracts of these samples. The stated dosage of 5 ppm in the diet was below the maximum expected dietary intake for dairy cattle; no tests were conducted at higher rates to enable characterization of residues. Additional information for the distribution and characterization of residues in milk, eggs, liver, kidney, muscle, and fat is required.

Crop residue data and plant and animal metabolism data are required. Once the Agency has received and reviewed these data, it will determine whether additional data are required for assessment of oxydemeton-methyl and its cholinesterase-inhibiting metabolites on various crops and for residues in animal products. Data on the magnitude and levels of residues of oxydemeton-methyl are sufficient for assessment of established tolerances for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on potatoes, sugar beet roots, turnip roots, sugar beet tops, turnip greens, onions (dry bulb), lettuce (head), broccoli, Brussels sprouts, lima beans, snap beans, lima bean vines, snap bean vines, peas, cucumbers, apples, pears, grapes, strawberries, filberts, sorghum grain, sorghum forage, corn forage and fodder, clover forage, mint hay, and safflower. The data support established tolerances for all of these commodities except for strawberries.

Data submitted for cauliflower are insufficient to ascertain the adequacy of the established tolerance for residues in or on cauliflower; however, currently available data on other crops translated to cauliflower adequately support the established tolerance.

Data or additional data are required to ascertain the adequacy of the established tolerances for cabbage, pea vines, pea straw, peppers, melons, oranges, apricots, plums (fresh prunes), blackberries, walnuts, field corn grain, sweet corn, alfalfa hay, clover hay, and cottonseed. Tolerances must be proposed and appropriate supporting residue data provided for bean hay, pecans, and alfalfa forage. Data are required to evaluate whether the current nonfood use classification is appropriate for cherries, peaches, bluegrass (forage and hay), and avocados.

Data requested for the appropriate crops listed in the previous paragraph will be used to fulfill outstanding requirements for data to evaluate the established tolerances for residues in or on eggplant, pumpkin, squash (winter and summer), grapefruit, lemons, and raspberries. Data required for the appropriate crops listed in the previous paragraph will be used to fulfill outstanding requirements for data to evaluate the adequacy of the current nonfood use classification for crabapples, quinces, and nectarines.

Processing studies are required for potatoes, sugar beets, grapes, corn, and cottonseed.

Analytical methodology for determining the levels of residues of oxydemeton-methyl in plants and animals is adequate for data collection for residues in plant commodities and in animal tissues. If additional metabolites of toxicological concern are found in or on plants and animals, additional methods, validation, and residue data (for representative commodities) may be required.

Storage stability data are sufficient to ascertain that oxydemeton-methyl and its cholinesterase-inhibiting metabolites are stable in or on alfalfa, apple, cabbage, green oat forage, and raspberry samples stored for up to 231 days at -23 to -18 °C. Oxydemeton-methyl was found to be stable in mint oil at 23 °C for up to 6 months. Stability data for wheat (presumably grain) samples indicate that 27 to 56 percent of oxydemeton-methyl residues and 46 to 49 percent of oxydemeton-methyl sulfone residues stored frozen for 671 days are decomposed to compounds not detected by the GLC method provided by the registrant. The data are too meager to make general conclusions concerning the stability of oxydemeton-methyl in plant commodities. No data are available depicting stability of any residues of oxydemeton-methyl in animal commodities. Additional storage stability data are required in order to evaluate the adequacy of numerous established tolerances and depicting the stability of the residues of concern under the conditions and for the time interval specified.

Monitoring data from the Food and Drug Administration (FDA) indicates that residues of oxydemeton-methyl and/or its sulfone have not been observed in domestic and imported foods and feeds analyzed during the period FY 78 to August 31, 1986 using methodology known to be capable of determining oxydemeton-methyl and/or its sulfone.

Dietary Exposure

The Acceptable Daily Intake (ADI) for residues of oxydemeton-methyl was previously based on a no-observed-effect-level (NOEL) for cholinesterase inhibition of 0.05 mg/kg/day obtained from a 60-day human study. Acute oral administration of a dosage level up to 0.5 mg/kg/day and oral administration of a dosage level of 0.05 mg/kg/day for up to 60 days were without noticeable effects on the human blood cholinesterase activities. With a safety factor of 10, the ADI was 0.005 mg/kg/day. Published tolerances occupied 81.77% of this ADI.

Based on a reproduction NOEL of 1 ppm (0.05 mg/kg/day) from a 2-generation reproduction study in rats, tolerances for oxydemeton-methyl have been reassessed. A comparison of published tolerances to the Reference Dose (RfD) was conducted using the Tolerance Assessment System Routine Chronic Analysis (TAS). Based on the NOEL of 1 ppm (0.05 mg/kg/day) and a safety factor of 100, the RfD is calculated to be 0.0005 mg/kg/day. The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population is 0.005 mg/kg/day. Therefore, existing published tolerances occupy approximately 1000% of the RfD. The majority of the TMRC was contributed by fresh apples and juice, orange juice, stone fruit, cereal grains, legume vegetables and milk. The exposure estimates provided by the TMRC may greatly overestimate actual dietary exposure, since the TMRC assumes residues at the tolerance level, 100% of crop treated, and no degradation of residues during the processing of food.

Because of the extensive residue chemistry and toxicology data gaps, the Agency cannot complete all tolerance reassessments. The tolerances will be reassessed when the required data are submitted and reviewed.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions

Based on review and evaluation of all available data on oxydemeton-methyl, the Agency has made the following determinations:

1. A Special Review on all uses of pesticide products containing oxydemeton-methyl, will be initiated based on concerns regarding potential reproductive effects.

Rationale: The Agency has determined that oxydemeton-methyl has the potential to induce reproductive effects in humans, and that that effect is of concern because of the potential exposure of applicators, mixers, and loaders who use products containing oxydemeton-methyl, and of field workers who may enter treated fields. Refer to sections III.A.1 and III.C. for a more detailed discussion of these concerns. The Agency is publishing its Notice of Special Review in the FEDERAL REGISTER, pursuant to 40 CFR 154.25(c), to coincide with the issuance of this Registration Standard.

2. Registrations must be amended to include certain interim risk reduction measures. Based on concerns regarding reproductive effects, the labeling of all products containing oxydemeton-methyl, either as a single active ingredient or in combination with other active ingredients, must contain language requiring, among other requirements, the use of maximum, full body protective clothing/equipment, and that all end-use products containing oxydemeton-methyl be classified for Restricted Use. The required label language and Restricted Use classification are set forth in section IV, D in this Registration Standard.

Rationale: The use of products containing oxydemeton-methyl by mixers/loaders/applicators, and the potential for exposure of field workers to oxydemeton-methyl in treated areas, may induce reproductive effects. The Agency estimates that the use of maximum protective clothing/equipment, closed systems, and restricting the use to certified applicators could increase the margins-of-safety roughly 10-fold, while additional data are generated which will allow the Agency to fully assess the potential risks from use of pesticide products containing oxydemeton-methyl.

3. No new tolerances and food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure to oxydemeton-methyl.

Rationale: Available residue chemistry and toxicology data for oxydemeton-methyl are not sufficient to reassess existing tolerances. Plant and animal metabolism data and residue data on various commodities are required. The pertinent toxicology data requirements include: chronic feeding/oncogenicity and mutagenicity (refer to Table A for residue chemistry and toxicology data requirements). Until these data are submitted and reviewed, the Agency cannot perform a tolerance reassessment.

4. The 48-hour reentry interval established under 40 CFR 170 for all agricultural uses of oxydemeton-methyl which may involve hand labor tasks will continue to be required. In addition, the use of maximum protective clothing and equipment as prescribed in Chapter IV.D. is required if treated fields are entered prior to the end of the reentry interval.

Rationale: The Agency has concerns regarding both acute and chronic exposure of agricultural workers to oxydemeton-methyl and residues. Through this Registration Standard, the Agency is requiring data to more precisely determine measures necessary to protect reentry workers from adverse effects due to ODM exposure. Until these data are received and reviewed, the 48-hour reentry interval and the protective clothing prescribed will minimize the risk to these workers from exposure during reentry into treated agricultural sites.

5. Droplet Spectrum and Spray Drift Field Evaluation tests are required. The droplet spectrum study must be performed to reflect the commonly-used nozzle and other equipment types which are used in the application of oxydemeton-methyl to fruit trees, and agricultural crops. The spray drift field evaluation must be performed to reflect the commonly-used application equipment, use patterns, and typical locations of use (including different weather factors). The spray drift field evaluation should specifically be conducted on agricultural crops.

Rationale: The Agency is concerned about hazards to nontarget organisms (fish and wildlife, domestic animals and humans) caused by drift from aerial applications of oxydemeton-methyl. These tests are required because of the toxic nature of oxydemeton-methyl and because these application methods may lead to exposure of bystanders and wildlife. These tests will indicate the extent of possible drift of this chemical from normal applications and the data from these tests will enable the Agency to evaluate the potential for drift.

6. The use of human flaggers is prohibited during aerial application, unless they are in totally enclosed vehicles.

Rationale: The Agency is imposing this requirement to minimize hazard to flaggers since human flaggers face a risk of exposure by direct contact or through drift during aerial application.

7. The telephone number of the National Pesticide Telecommunications Network (1-800-858-7378) must be included on the label of all oxydemeton-methyl products that are classified as Toxicity Category I or II (bearing the DANGER or WARNING signal words).

Rationale: The telephone number is included in order to provide an additional source of first aid information in the event of a pesticide accident.

8. End-use product labeling must contain personal hygiene information and requirements for cleaning of protective clothing and equipment after working with oxydemeton-methyl products.

Rationale: Because of the toxicity of many of these products and the number of incidents reported, the Agency believes this requirement is necessary to prevent poisonings of workers or other household members through secondary exposure to contaminated personal and protective clothing.

9. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to recieve priority review as soon as they are received by the Agency:

§158.125 - Residue Chemistry

171-4 - Nature of Residue (Metabolism)
- Plants
- Livestock

§158.130 - Environmental Fate

162-1 - Aerobic Soil Metabolism
163-2 - Laboratory Volatility
164-1 - Field Dissipation Studies - Soil
165-1 - Confined Rotational Crop

§158.135 - Toxicology

84-2 - Chromosomal Aberration
- Other Mechanisms of Mutagenicity

Special Testing
- Male Short Term Exposure Study
- Male Reproductive System Toxicity Study

§158.140 - Reentry

132-1 - Foliar Dissipation
132-2 - Soil Dissipation
133-3 - Dermal Exposure
133-4 - Inhalation Exposure

§158.142 - Spray Drift

201-1 - Droplet Size Spectrum
202-1 - Drift Field Evaluation

10. While the required data are being developed, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing oxydemeton-methyl may be sold, distributed, formulated and used subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration because data are missing or are inadequate [see FIFRA section 3(c)(2)(B) and 3(c)(7)]. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain oxydemeton-methyl, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in section C below.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products must contain oxydemeton-methyl as the sole active ingredient. Each manufacturing-use formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing products containing oxydemeton-methyl provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into other manufacturing-use products or into end-use products labeled for federally registered uses. The Use Index in Appendix III lists all registered uses as well as approved maximum application rates and frequencies.

The use patterns currently registered for oxydemeton-methyl are:

Terrestrial - Food Crop: alfalfa (seed); apple (nonbearing); apricot (nonbearing); avocado (nonbearing)*/**; blackberry; bluegrass (seed crop)*/**; broccoli; Brussels sprouts; cabbage; cauliflower; cherry (nonbearing)**; citrus (nonbearing); clover (seed); corn; cotton; crabapple (nonbearing)**; cucumber; eggplant; filbert; grapefruit; grapes; grapes (nonbearing); lemon; orange; lettuce (head); lima beans; mint (including spearmint and peppermint); muskmelon; nectarine (nonbearing); onion (Spanish dry bulb); orange; peach (nonbearing)*/**; pear; peas; pecan (nonbearing)**; peppers; plum; potato;

prune; pumpkin; quince (nonbearing)**; raspberry; snap beans; sorghum; strawberry; sugar beets; summer squash; turnips; walnut; walnut (nonbearing) watermelon; winter squash.

Terrestrial - Nonfood Crop: christmas tree plantations*; ornamental flowering plants and trees; (including chrysanthemum, cuban laurel, dahlia, and roses; ornamental lawns and turf; ornamental nursery stock*; ornamental woody plants.

Greenhouse - Nonfood Crops: Agricultural crops-research crops (not for consumption)*.

Domestic - Outdoor: domestic dwellings - building foundations, along fences, shrubbery areas.

Domestic - Indoor: houseplants

Forestry - Ornamental plants and forest trees - injection treatment, cedar, juniper, cottonwoods, cypress, Douglas fir, elms, pines (excluding pinyon pine), redwood, spruce; Douglas fir seed and breeding orchards*.

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* This use is currently registered as a Special Local Need registration under 24(c) of FIFRA.

** These crops, previously considered nonfood uses must be supported by residue chemistry data for continued registration.

D. Required Labeling

All products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and below. Appendix II contains information on label requirements.

Pesticide products containing oxydemeton-methyl as an active ingredient, either singly or in combination with other active ingredients, may not be released for shipment by the registrant after January 15, 1988, unless the product bears amended labeling which complies with the requirements of this Standard. Five (5) copies of the labeling, revised in accordance with this Standard, must be submitted prior to release for shipment.

Pesticide products containing oxydemeton-methyl as an active ingredient, either singly or in combination with other active ingredients, may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after April 15, 1988 , unless the product bears amended labeling, five copies of which have been submitted to the Agency, which complies with the requirements of this Standard.

The following information must appear on manufacturing-use and end-use products:

Ingredient Statement

The ingredient statement for all oxydemeton-methyl products must list the active ingredient as:

ACTIVE INGREDIENT:
S-[2-(Ethylsulfinyl)ethyl]O,O-dimethyl
phosphorothioate . . . . ____%
INERT INGREDIENTS: . . . . ____%

1. Manufacturing-Use Product Labeling

a. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into other manufacturing-use products or end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Appendix III. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

b. Environmental Hazards Statement

The following revised environmental hazard statement must appear on all manufacturing-use product labels:

> "This pesticide is toxic to fish. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

c. Use of Closed Systems for Mixing and/or Loading

The labeling of all MPs must contain the following in the directions for use:

> "Closed systems for mixing and/or loading this product must be capable of removing the pesticide from the shipping container, rinsing the container, and transferring the pesticide and the rinsate into mixing tanks and/or application equipment. Protective clothing and equipment, specified in the pesticide labeling must also be used when mixing and/or loading this pesticide."

d. Protective Clothing, Equipment and Work Safety Statements

The following protective clothing, equipment and work safety statements must appear on the labeling of all MPs.

> "REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.
>
> Do not rub eyes or mouth with hands. If you feel sick in any way, STOP WORK and get help right away. See First Aid (Practical Treatment) section of label.
>
> If handled indoors, provide mechanical exhaust ventilation.

HANDLE THIS PRODUCT ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II.

IF MIXING AND/OR LOADING IN A CLOSED SYSTEM WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.

Wear long sleeve shirt and long legged pants. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, take off all clothing and shoes. Shower using soap and water. Wear only clean clothes. Do not wear contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Personal and protective clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with oxydemeton-methyl must be destroyed according to state and local regulaltions. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED."

2. End-Use Product Labeling

All end-use products containing oxydemeton-methyl as an active ingredient, either singly or in combination with other active ingredients, must bear the following labeling statements:

a. Restricted Use Statement

The following statement must appear on the front panel of all end-use products:

> "RESTRICTED USE PESTICIDE
> Due to Reproductive Effects
>
> For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Direct supervision for this product is defined as the certified applicator being physically present during mixing, loading, equipment repair, and equipment cleaning. Certified applicators must ensure that all persons involved in these activities under their direct supervision are informed of the precautionary statements."

b. Reentry Interval

The following statement must appear on the labeling of all agricultural end-use products which are applied to crops whose culture may involve hand labor tasks:

> "DO NOT ENTER TREATED AREAS FOR 48 HOURS AFTER APPLICATION UNLESS PROTECTIVE CLOTHING AND EQUIPMENT, AS PRESCRIBED IN THIS LABELING, ARE USED."

c. Use of Closed Systems for Mixing and/or Loading

The labeling of all end-use products must contain the following in the directions for use:

> "Closed systems for mixing and/or loading this product must be capable of removing the pesticide from the shipping container, rinsing the container, and transferring the pesticide and the rinsate into mixing tanks and/or application equipment. Protective clothing and equipment, specified in the pesticide labeling must also be used when mixing and/or loading this pesticide."

d. Protective Clothing, Equipment and Work Safety Statements

The following protective clothing, equipment and work safety statements must appear on the labeling of all end-use products:

> "REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.
>
> Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.
>
> Do not rub eyes or mouth with hands. If you feel sick in any way, STOP WORK and get help right away. See First Aid (Practical Treatment) section of label.
>
> If handled indoors, provide mechanical exhaust ventilation.
>
> HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.
>
> Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II.
>
> IF MIXING AND/OR LOADING IN A CLOSED SYSTEM WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.
>
> Wear long sleeve shirt and long legged pants. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, AND DURING EARLY REENTRY TO TREATED AREAS.

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves and chemical resistant boots, shoes, or shoe coverings.

DURING APPLICATION ONLY FROM A TRACTOR WITH A COMPLETELY ENCLOSED CAB OR AERIALLY WITH AN ENCLOSED COCKPIT WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.

Wear long sleeve shirt and long legged pants, chemical resistant boots, shoes, or shoe coverings. Clean chemical resistant gloves must be available in the cab/cockpit and must be worn while exiting. This clothing is inadequate to protect you during equipment repair, cleaning or reentry.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking or toileting.

AFTER WORK, take off all clothing and shoes. Shower using soap and water. Wear only clean clothes. Do not wear contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Personal and protective clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with oxydemeton-methyl must be destroyed according to state and local regulaltions. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

FLAGGING: Human flaggers are prohibited unless in totally enclosed vehicles"

e. Environmental Hazards Statements

The following environmental hazard statement must appear on the label of all end-use products:

> "This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites."

f. Bee Precaution Statement

Products intended for outdoor use must bear the following bee precaution statement on product label:

> "This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The labeling requirements specified for manufacturing-use products in Section IV.

3. The data requirements listed in Table A.

C. End-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C (if included).

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

D. End-use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end-use product.

2. If not eligible for the formulator's exemption, the data requirements listed in Table A and Table C (if included).

3. If eligible for the formulator's exemption, the data requirements listed in Table C (if included).

4. The labeling requirements specified for end-use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.F.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing-Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

   d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. By January 15, 1988 or April 15, 1988, you must submit to the Product Manager, five copies of labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration/Amendment (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Product Specific Data Report (EPA Form 8580-4).

4. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. By January 15, 1988 or April 15, 1988, you must submit to the Product Manager, five copies of labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End-Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. By January 15, 1988 or April 15, 1988, you must submit to the Product Manager, five copies of labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

D. End-Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. By January 15, 1988 or April 15, 1988, you must submit to the Product Manager, five copies of labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C (if included).

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

E. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

1. These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

2. In addition, by January 15, 1988 or April 15, 1988, you must submit to the Product Manager, five copies of labeling, as specified in Chapter IV.D. Required Labeling, including the container label and any associated supplemental labeling must be submitted. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

F. Addresses

The required information must be submitted to the following address:

William H. Miller (PM 16)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	1/	1/	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	1/	1/	Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	1/	1/	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	1/	1/	Yes	12 Months
62-2 - Certification of Limits	TGAI	All	1/	1/	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All	1/	1/	Yes	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	1/	1/	Yes	6 Months
63-3 - Physical State	TGAI	All	1/	1/	Yes	6 Months
63-4 - Odor	TGAI	All	1/	1/	Yes	6 Months
63-5 - Melting Point	TGAI	All	1/	1/	Yes	6 Months
63-6 - Boiling Point	TGAI	All	1/	1/	Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	1/	1/	Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	1/	1/	Yes	6 Months
63-9 - Vapor Pressure	PAI	All	1/	1/	Yes	6 Months
63-10 - Dissociation Constant	PAI	All	N/A	-	-	-
63-11 - Octanol/Water Partition Coefficient	PAI	All	1/	1/	Yes	6 Months
63-12 - pH	TGAI	All	N/A	-	-	-
63-13 - Stability	TGAI	All	1/	1/	Yes	6 Months
Other Requirements						
64-1 - Submittal of Samples	TGAI, PAI	All	-	-	Reserved3/	

TABLE A

GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

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§158.120 Product Chemistry Footnotes

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

3/ If samples are needed, the Agency will request them.

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry					
171-2 - Chemical Identity[3]/	-	-	-	-	
171-3 - Directions for Use	-	(See Index)	-	-	
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA & Metabolites	Partially	00116221 00120079	Yes[4]/[5]/	10/14/87[2a]/
- Livestock	PAIRA & Metabolites	Partially	00120208	Yes[6]/[7]/	10/14/87[2a]/
171-4 - Residue Analytical Method					
- Plant Residues	TGAI & Metabolites	Partially	00028722 00029432 00037507 00037509 00038082 00038467 00038468 00074357 00096458 00107030 00120078 00120208 00120209 00124231 00152371 00156398	Reserved[8]/[9]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Residue Analytical Method (cont'd)					
- Animal Residues	TEP & Metabolites	Partially	00038082	Reserved[8]/[9]/	
171-4 - Storage Stability Data	TEP & Metabolites	Partially	00037508 00067459 00095522 00152371	Yes[10]/[11]/	24 Months
171-4 - Magnitude of the Residue [74]/ - Crop Field Trials [74]/					
- Root & Tubers Group[12]/[13]/	TEP				
° Potatoes	TEP	Partially	00068261 00095522 00117130 00152371	Yes[14]/	04/14/88[2a]/
° Sugar Beets	TEP	Yes	00095522 00095523 00120079	No[15]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance1/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Turnips	TEP	Yes	00107030	No	
- Leaves of Root and Tubers Group 16/					
° Sugar Beet Tops	—	Yes	00095522 00095523 00120079 00115760	No	
° Turnip Greens	—	Yes	00107030	No	
- Bulb Vegetables Group17/					
° Onions (Dry Bulb)	—	Yes	00115760	No	
- Leafy Vegetables Group18/					
° Lettuce	—	Yes	00038077 00067474 00074356 00120079	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.125 Residue Chemistry					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
- Brassica Leafy Vegetable Group[19][20]					
° Bok Choy	--	--	--	Reserved[21]	
° Broccoli	--	Yes	00075906 00117130 00158208 00158209	No	
° Brussels Sprouts	--	Yes	00070840 00120207 00124231	No	
° Cabbage	EP	Partially	00095522	Yes[22]	04/14/88[2a]
° Cauliflower	EP	Partially	00120207	No [23]	
° Collards	--	--	--	Reserved[21]	
° Kale	--	--	--	Reserved[21]	
° Kohlrabi	--	--	--	Reserved[21]	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
- Legume Vegetables Group[24]/[25]/					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Beans	--	Yes	00033834 00038462 00038463 00038464 00152371	No	
° Peas	—	Yes	00036270 00384634 00152371	No	
- Foliage of Legume Vegetables Group[26]/[27]/[28]/					
° Bean Vines & Hay	EP	Partially	00033834 00038462 00038463 00038464 00152371	Yes[29]/	04/14/88[2a]/
° Pea Vines & Straw	EP	Partially	00036270 00038464 00152371 00036269	Yes[30]/	04/14/88[2a]/

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1/]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2/]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
- Fruiting Vegetables Group[31/]/[32/]					
° Eggplant	EP	Partially	00075906 00107031	Yes[33/]	04/14/88[2a/]
° Peppers	EP	Partially	00075906 00107031	Yes[33/]	04/14/88[2a/]
- Cucurbit Vegetables Group[34/]					
° Cucumbers	--	Yes	00107030	No	
° Melons	EP's	Partially	00095522	Yes[35/]/[36/]	04/14/88[2a/]
° Pumpkins	EP	Partially	00095522 00152371	Yes[36/]	04/14/88[2a/]
° Squash	EP	Partially	00095522	Yes[36/]	04/14/88[2a/]
- Citrus Fruits Group[37/]					
° Grapefruit	EP	Partially	00075906 00107031	Yes[38/]	04/14/88[2a/]
° Lemon	EP	Partially	00075906 00107031	Yes[38/]	04/14/88[2a/]

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1/]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2/]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Orange	EP	Partially	00075906 00107031	Yes[38/]	04/14/88[2a/]
- Pome Fruits Group[39/]					
° Apple	EP	Yes	00037505 00075906 00107031	No	
° Crabapple	EP	No	—	Yes[40/]	04/14/88[2a/]
° Pears	—	Yes	00107030	No	
° Quince	EP	No	—	Yes[41/]	04/14/88[2a/]
- Stone Fruits Group[42/]					
° Apricots	EP	Partially	00103284 00152371	Yes[43/]	04/14/88[2a/]
° Cherries	EP	No	—	Yes[44/]	04/14/88[2a/]
° Nectarines	EP	No	—	Yes[45/]	04/14/88[2a/]

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Peaches	EP	Partially	00075906 00096458 00107031 00152371	Yes[46]	04/14/88[2a]
° Plums (fresh prunes)	EP	Partially	00107031 00120076	Yes[47]	04/14/88[2a]
- Small Fruits and Berries Group[48]/[49]					
° Blackberries	EP	Partially	00095522	Yes[50]	04/14/88[2a]
° Grapes	TEP	Partially	00038076 00038087	Yes[51]	04/14/88[2a]
° Raspberries	EP	Partially	00095522	Yes[50]	04/14/88[2a]
° Strawberries	EP	Partially	00120078 00141183 00152371	Yes[52]	04/14/88[2a]
- Tree Nuts Group[53]/[54]					
° Filberts	--	Yes	00067459 00115760	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Pecans	EP	No	--	Yes[55]/[56]/	04/14/88[2a]/
° Walnuts	EP	Partially	00075902 00075903 00115769 00152371	Yes[57]/	04/14/88[2a]/
- Cereal Grains Group[58]/[59]/[60]/					
° Corn, field and fresh	EP	Partially	00044956 00090456 00107030 00152371	Yes[61]/[62]/[63]/	04/14/88[2a]/
° Sorghum	--	Yes	00038079 00135473 00152371	No	
- Forage, Fodder, and Straw of the Cereal Grains Group[64]/					
° Corn forage, fodder, and silage	--	Yes	00044956 00090456 00107030 00152371	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
° Sorghum Forage, Fodder, Hay, and Silage	--	Yes	00038079 00135473 00152371	No	
- Grass Forage, Fodder, and Hay Group[65]					
° Bluegrass	EP	No	--	Yes[66]	04/14/88[2a]
- Nongrass Animal Feeds and Forage, Fodder, Straw, and Hay Group[67]					
° Alfalfa	EP	Partially	00090456 00120209 00152371	Yes[68]	04/14/88[2a]
° Clover	EP	Partially	00052038 00120209 00152371	Yes[69]	04/14/88[2a]
- Miscellaneous Commodities					
° Avocado	EP	No	--	Yes[70]	04/14/88[2a]

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL (cont'd)

Data Requirement	Test Substance[1]/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Crop Field Trials (cont'd)					
- Miscellaneous Commodities (cont'd)					
° Cotton	EP/TEP	Partially	00117130	Yes[71]/[72]/	04/14/88[2a]/
° Mint	EP	Yes	00037506 00037508 00037510	No	
° Safflower	--	Yes	00038078 00038082	No	
- Meat/Milk/Poultry/ Eggs	--	Partially	00036270 00036271 00036272 00036273 00038082 00118527 00140798	Reserved[73]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL
FOOTNOTES

1/ Test substance: TGAI = Technical Grade Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled: TEP = Typical End-Use Product; EP = End-Use Product.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless othewise specified.

2a/ These data requirements were previously imposed as part of the Agency's 3(c)(2)(B) Call-In Notice of April 9, 1986. These submittal due dates reflect the timeframes imposed in that Call-In Notice.

3/ Refer to product chemistry data requirement tables.

4/ The uptake, distribution and metabolism of [^{14}C]oxydemeton-methyl in a representative leafy vegetable, a root crop, and a small grain crop following foliar applications. Plants must be sampled at regular intervals up to at least 21 days after treatment to characterize residues. All major components of the terminal residues in mature plant parts must be identified (and confirmatory analytical procedures used to verify identification) and quantitated. If the metabolism of oxydemeton-methyl in these three crops differs significantly, then metabolism data for one representative commodity from each crop group for which a registered use of oxydemeton-methyl exists will be required.

5/ Representative samples from these tests must also be analyzed by enforcement methods to ascertain that these methods are capable of determining all metabolites of concern.

6/ Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed for 3 days with [^{14}C]oxydemeton-methyl at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

7/ Samples from the studies requested above should also be analyzed using current enforcement methods to ascertain the validity of these methods. Upon receipt of the requested data, the need for, and nature of, tolerances for residues in animal products will be determined.

8/ The colorimetric and GLC analytical methods have been validated for detection of oxydemeton-methyl and oxydemeton-methyl sulfone only, although all of the submitted methods conceivably could detect additional metabolites, if present, since the sample extract is oxidized before detection. Additional methods, validation data, and residue data (for representative commodities) may be required if the metabolism studies requested in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" reveal additional metabolism of toxicological concern in or on plants or in animals.

9/ Methodology which determines each metabolite of concern in plant and animal commodities separately may also be required.

Footnotes (cont'd)

10/ Required are data depicting the percent decline in residues over each sample storage interval and under conditions specified for each sample of all plant and animal commodities for which tolerances for oxydemeton-methyl are established, except that storage stability data are not required as long as the samples used to supply any required data on plant commodities are stored at ≤ -18 °C for no more than 231 days. On receipt of these data, the adequacy of all established tolerances will be reevaluated.

11/ All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples. These data must be accompanied by data depicting the stability of the residues of concern under the conditions and for the time intervals specified.

12/ Additional data to support the established tolerance for residues of oxydemeton-methyl in or on the representative group member sugar beets.

13/ Use directions must be proposed and appropriate supporting residue data submitted for the additional representative group members carrots and radishes.

14/ Data depicting oxydemeton-methyl residues of concern in or on potato chips, granules, and dried potatoes processed from potatoes bearing measurable, weathered residues. If residues concentrate during processing, appropriate food/feed additive tolerances must be proposed.

15/ Data depicting oxydemeton-methyl residues of concern in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable, weathered residues. If residues concentrate in these processed products, appropriate food/feed additive tolerances must be proposed.

16/ A crop group tolerance is inappropriate because registered uses for crop members differ. Currently, registered uses for leaves of sugar beets and turnips, respectively, involve maximum single application rates of 0.75 and 0.5 lb/ai/A; maximum numbers of seasonal applications of six and two; PHI's of 30 and 28 days; and tolerances of 0.5 and 2 ppm for oxydemeton-methyl residues.

17/ Use directions must be proposed, and appropriate supporting residue data submitted for green onions and one additional group member.

18/ Use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members leaf lettuce, celery, and spinach.

19/ Additional data are required to support the established tolerance for residues of oxydemeton-methyl in or on the representative group member cabbage.

20/ A tolerance and use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member mustard greens.

Footnotes (cont'd)

21/ No conclusions may be made at the present time regarding the adequacy of proposed tolerances for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on bok choy, collards, kale, and kohlrabi, and the grain, hay, and straw of wheat because available data are currently under review by EPA.

22/ Data depicting oxydemeton-methyl residues of concern in or on cabbage harvested 7 days following the last of three foliar applications of the 2 lb/gal EC formulation at 0.5 lb ai/A. Separate tests must be conducted using ground and aerial ULV application equipment. Tests must be conducted in Florida(16%), Texas(16%), New York(15%), Wisconsin(9%), and California(8%); these States represent the major regions of U.S. cabbage acreage (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, pp. 338-339).

23/ The available data are sufficient to support the established tolerance for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on cauliflower by translation from broccoli. Since all of the submitted tests depicted residues in or on cauliflower resulting from exaggerated rates, these data are insufficient to indicate whether residues would exceed the established tolerance under currently registered uses. No additional data are required for this topic.

24/ Residue data supporting the proposed tolerance and use for dry beans will be required.

25/ Use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member soybeans.

26/ Additional data are required to support the established tolerances for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on pea vines and pea straw.

27/ Additional data are required to support a tolerance for residues in or on bean hay and an appropriate tolerance should be proposed for this commodity based upon the requested data.

28/ Use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member soybean.

29/ A tolerance must be proposed and supporting data submitted depicting residues of concern of oxydemeton-methyl in or on hay from succulent bean varieties harvested 21 days after last of three foliar applications of an EC at 0.5 lb ai/A. Separate tests must be conducted using ULV, aerial, and ground equipment for application. Tests must be conducted in California(40%) and Delaware(20%), which collectively account for ca. 60% of U.S. lima bean acreage (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, p. 336) and in New York(12%), Oregon(59%), and Wisconsin(35%), States which collectively account for ca. 66% of U.S. snap bean production (Agricultural Statistics 1985, p. 149).

30/ Data are required depicting oxydemeton-methyl residues in or on vines and straw of peas treated with the 2 lb/gal EC formulation at 0.375 lb ai/A in three applications using ground, ULV, and aerial equipment

Footnotes (cont'd)

in separate tests. Tests must be conducted in five locations representative of the northcentral United States. Samples must be collected at the 21-day PHI.

31/ Additional data are required to support the established tolerance for residues of oxydemeton-methyl in or on the representative group member peppers.

32/ Use directions must be proposed and appropriate supporting residue data submitted for one additional representative group member, tomatoes.

33/ Data are required depicting residues of concern of oxydemeton-methyl in or on peppers harvested on the same day after the last of two foliar treatments with the 2 lb/gal EC formulation at 0.5 lb ai/A. Tests must be conducted in California(20%), Florida(19%), New Jersey(18%), and New Mexico(13%) or Texas(15%) accounting for ca. 75% of U.S. hot and sweet pepper acreage (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, pp. 349-350). Separate tests must include applications with ground and aerial ULV equipment. (These data will be translated to assess the established tolerance for eggplant.)

34/ Additional data are required to support the established tolerance for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on the representative group member melons.

35/ Data are required depicting residues of concern in or on melons following ULV foliar applications (in ≥ 1 gal spray/A) at 0.5 lb/ai/A with aerial equipment, as follows: Tests with muskmelons must be conducted in California (2%), Indiana(2%), and Texas(21%), States which collectively account for ca. 75% of U.S. cantaloupe production (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, p. 339). Muskmelons must be harvested 14 days after the last of three applications. Tests with watermelons must be conducted in North Carolina(4%) and Texas(24%) collectively accounting for ca. 28% of U.S. watermelon acreage and representative of the major production regions (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, pp. 356-357). Watermelons must be harvested 7 days after the last of two applications.

36/ Data depicting residues of concern in or on melons harvested 7 days following the last of three applications of the 25% WP formulation at 0.5 lb ai/A in 50 to 100 gal water. Applications must be made using ground equipment, and in separate tests, aerial equipment. The tests must be conducted in Hawaii. Alternatively, the registrant may elect to cancel this use permitted under EPA Registration No. 37843-8563. (These data will be translated to assess the established tolerance for pumpkins and squash.)

37/ Additional data are required for oxydemeton-methyl residues of concern in or on citrus fruits from the registered uses with aerial and ULV applications.

38/ Data are required depicting oxydemeton-methyl residues of concern in or on oranges harvested 7 days after the last of two foliar aerial applications (ULV applications must be included) of the 2-lb EC formulation at 0.375 lb ai/A. Tests must be conducted in California(29%) and Florida(69%) to represent ca. 98% of U.S. commercial orange production (Agricultural Statistics 1985, p. 198). (These data will be translated to assess the established tolerances for grapefruit and lemons.)

Footnotes (cont'd)

39/ A crop group tolerance is not appropriate at this time because the registered uses among the group members apples and pears differ. Maximum use rates are 0.375 and 0.2 lb ai/A, respectively for apples and pears, respective tolerances are 1 ppm and 0.3 ppm, and respective PHI's are 365 and 30 days.

40/ There are no available data to support a nonfood use classification for the use of oxydemeton-methyl formulations on nonbearing crabapple trees. However, the data submitted for apples will be translated to crabapples. Based on these data a 1.0 ppm tolerance for crabapples would be appropriate. A tolerance proposal is needed.

41/ There are no available data to support a nonfood use classification for the use of oxydemeton-methyl formulations on nonbearing quince trees. However, the data submitted for apples will be translated to quinces. Based on these data, a 1 ppm tolerance for quinces would be appropriate. A tolerance proposal is needed.

42/ A crop group tolerance is not appropriate at the present time because the registered uses markedly differ. Uses for the representative commodity plum (or fresh prunes) include soil drenches in addition to the foliar applications registered for other members of the stone fruits group. In addition, three different tolerance levels are established for members of this group: nonfood for cherries, nectarines, and peaches, 0.5 ppm for apricots; and 1 ppm for plums.

43/ Required are data depicting residues of concern of oxydemeton-methyl in or on apricots 1 year after multiple foliar applications of the 2 lb/gal EC at 0.375 lb ai/100 gal and after ULV applications with aerial equipment at 0.375 lb ai/A in separate tests. The registrant must propose a maximum number of applications or a maximum total application rate per year. Tests must be conducted in California(91%), Michigan(1%), and Washington(4%), States which collectively account for ca. 96% of U.S. apricot production (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept of Commerce, pp. 359-360).

44/ Required are data depicting residues of concern of oxydemeton-methyl in or on cherries harvested 1 year after multiple foliar applications of the 2 lb/gal EC at 0.375 lb ai/100 gal of spray suspension. The registrant must propose a maximum number of applications or a maximum total application rate per year. Tests must be conducted in California(19%), Michigan(22%), New York(2%), and Washington(35%), States which collectively account for ca. 78% of U.S. sweet and sour cherry production (Agricultural Statistics 1985, p. 211) including tests with both sweet and sour cherry varieties in Michigan and New York.

45/ No data have been submitted depicting residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on nectarines resulting from the registered uses. However, no data are required since data required for apricots and peaches will be translated to nectarines to evaluate the current nonfood classification for the registered used on nectarines. [We note that if residues from the registered foliar applications differ significantly for apricots and peaches, then additional data may be required for nectarines.]

Footnotes (cont'd)

46/ Depiction of residues of concern of oxydemeton-methyl in or on peaches harvested 1 year after multiple foliar applications of the 2 lb/gal EC at 0.375 lb ai/100 gal of spray suspension. The registrant must propose a maximum number of applications or a maximum total application rate per year. Tests must be conducted in California (56%) and South Carolina(18%), States which collectively account for ca. 74% of U.S. peach production (Agricultural Statistics 1985, p. 211).

47/ Required data depicting oxydemeton-methyl residues of concern in or on plums harvested 35 days after the last two foliar aerial applications (ULV applications must be included) of the 2 lb/gal EC formulation at 0.25 lb ai/A. Tests must be conducted in California(89%) and Michigan(4%) to represent ca. 93% of U.S. plum production (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, p. 365).

48/ Additional data to support the established tolerance for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on the representative group member blackberries or other Rubus ssp.

49/ Revised directions must be proposed and appropriate supporting residue data submitted for the additional representative group member strawberries since residues exceed the established tolerance under the currently registered uses. Alternatively, if Toxicology Branch approves, an increase in the established tolerance could be proposed that would be consistent with the submitted data.

50/ Data are required depicting residues of concern 7 days following foliar application with the 2 lb/gal EC formulation at 3 lb ai/100 gal applied as a full cover spray in 600 gal/A. Application must be made using ground equipment, and in separate tests, aerial equipment. Applications must include ULV treatment in at least 1 gal water/A. The tests must be conducted in Oregon which comprises ca. 76% of the U.S. blackberry crop (1982 Census of Agriculture, Vol. 1, Part 51, U.S. Dept. of Commerce, p. 370). (These data will be translated to assess the established tolerance for raspberries.)

51/ Data are required depicting residues of concern in or on raisin waste processed from grapes bearing measurable weathered residues. Conclusions regarding the adequacy of the proposed food/feed additive tolerance for residues in raisin waste cannot be made at this time.

52/ The submitted data do not support the established tolerance for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on strawberries treated at the maximum rate and harvested at the 3-day PHI. Residues in or on one such strawberry sample exceeded the tolerance level by a factor of four. Any proposed increase in the established tolerance must be approved by the Toxicology Branch. The registrant may elect to cancel this use on strawberries or amend current use directions (increase PHI or decrease application rate or number) and provide data reflecting the amended use directions.

Footnotes (cont'd)

53/ Use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member almond.

54/ Residue data to support the proposed tolerances for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on pecans and pecan hulls are currently under review. We note that proposed use directions for pecans differ significantly from those for filberts and walnuts, and the proposed tolerance for pecans differs by ≥ 5X from the tolerance established for walnuts.

55/ Conclusions regarding the adequacy of the proposed tolerances for residues in or on pecans and pecan shells resulting from the proposed foliar use cannot be made because the data are currently under review. If this tolerance is approved for the proposed foliar use, the need for data reflecting injection use will be obviated; otherwise, refer to footnote56/for data requirements.

56/ A tolerance must be proposed and appropriate supporting data submitted for pecans 1 year following injection of the 50% P/T at 1 unit/4-6 in circumference of the trunk at the base of the tree.

57/ Data are required depicting oxydemeton-methyl residues of concern in or on walnut meats harvested 30 days after one foliar application of the 2 lb/gal EC at 0.375 lb ai/A made with aerial equipment, ULV applications must be included in the required tests. Tests must be conducted in at least three locations in California representing diverse agricultural practices for walnut production. California accounts for ca. 100% of U.S. walnut production (Agricultural Statistics 1985, p. 235).

58/ Additional data are required to support the established tolerance for residues of oxydemeton-methyl in or on the representative crop group member, corn.

59/ Use directions must be proposed, and appropriate supporting residue data submitted for one additional representative crop, rice.

60/ Available data in support of the proposed tolerance for oxydemeton-methyl residues in or on the representative crop wheat are currently under review. Additional data may be required.

61/ Data are required depicting residues of concern of oxydemeton-methyl in or on field corn grain and sweet corn kernels plus cobs (husks removed) treated foliarly with the 2 lb/gal EC formulation. Samples must be harvested in separate tests 7 days after one application at 0.5 lb ai/A and 21 days after three applications at 0.5 lb ai/A. Separate tests must be conducted using ground and ULV aerial equipment for applications. Tests must be conducted in Iowa (19%), Illinois(9%), Indiana(9%), Minnesota(9%), and Nebraska(10%); (numbers in parentheses following each State

Footnotes (cont'd)

are percentages of U.S. corn for grain production (Agricultural Statistics 1985, p. 32); in Minnesota(20%), Oregon (11%), Washington(8%), and Wisconsin(19%); numbers in parentheses following each State represent percentages of U.S. sweet corn production (Agricultural Statistics 1985, p. 156).

62/ Data are required depicting oxydemeton-methyl residues of concern in milled products, crude oil, and refined oil processed from field corn bearing measurable, weathered residues. If residues concentrate during processing, appropriate food/feed additive tolerances must be proposed.

63/ Data are required depicting oxydemeton-methyl residues of concern in or on field corn grain harvested 14 days after the last of three applications of the 2 lb/gal EC at 0.5 lb ai/A to support the SLN registration in Kansas (SLN KS800010) and depicting residues in or on field corn grain and in or on sweet corn kernels plus cobs harvested 7 days after the last of three applications of the 2 lb/gal EC at 0.5 lb ai/A to support the SLN registration in Utah (SLN UT760001). Alternatively, the registrant may elect to cancel these uses permitted under SLN's KS800010 and UT760001.

64/ A crop group tolerance is not appropriate at the present time because data submitted in support of the proposed tolerances for wheat hay and straw are currently under review.

65/ Use directions must be proposed and appropriate residue data submitted for the additional representative group members Bermudagrass and bromegrass or fescue.

66/ Data are required depicting residues of oxydemeton-methyl in or on bluegrass forage and hay harvested following multiple foliar applications at 1 lb ai/A. Separate tests with ULV and high-volume equipment must be included. An appropriate maximum seasonal rate or number of applications must be specified and supported by the data. Tests must be conducted in Idaho, Oregon, and Washington. If residues are detected, a tolerance must be proposed or, alternatively, the registrant may elect to cancel SLN's ID770017, OR800070, and WA770018.

67/ Additional data are required to support the established tolerances for residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in or on the representative group members alfalfa and clover.

68/ Data are required depicting oxydemeton-methyl residues of concern in or on alfalfa hay and alfalfa forage harvested 21 days after the last of multiple aerial applications of an EC at 0.5 lb ai/A. Tests must be conducted in Idaho, Nevada, Oregon, Utah, and Washington; the States for which applications with aerial equipment are registered. ULV applications must be included in the required tests. The registrant must also propose a maximum number of application per season or a maximum seasonal use rate.

Footnotes (cont'd)

69/ Data are required depicting oxydemeton-methyl residues of concern in or on clover hay harvested 21 days following the last of multiple foliar applications of the 2 lb/gal EC formulation at 0.5 lb ai/A. The registrant must propose a maximum number per season or a maximum seasonal use rate. The tests must be conducted in Oregon(30%), Illinois (10%), Minnesota(10%), California(9%), Montana(6%), and Michigan(5%), States which comprise 70% of the U.S. clover seed crop (Agricultural Statistics, 1981, pp. 280-281).

70/ Data are required depicting oxydemeton-methyl residues of concern in or on fruit of avocado trees treated a non-bearing year with the lb/gal EC formulation in multiple foliar applications at 0.0625 oz/gal. Fruit must be harvested 12 months after the final application. The registrant must specify a maximum seasonal application or number of applications per season supported by the required data. The tests must be conducted in California. Alternatively, the registrant may elect to cancel this use permitted under CA790215.

71/ Data are required depicting oxydemeton-methyl residues of concern in or on cottonseed harvested 14 days following the last of the three foliar applications of the 2 lb/gal EC formulation at 0.5 lb ai/A. Applications must be made with ground equipment and, in separate tests, aerial equipment, including ULV applications. Tests must be conducted in California(22%), Michigan(18%), and Texas(29%), States which represent ca. 69% of U.S. commercial cotton production (Agricultural Statistics 1985, p. 62).

72/ Data are required depicting oxydemeton-methyl residues of concern in processed commodities (hulls, meal, soapstock, and crude and refined oils) of cotton bearing measurable weathered residues. Should residues concentrate, appropriate food/feed additive tolerances must be proposed.

73/ Upon receipt of the data requested in the section entitled "Nature of the Residue in Animals," the established tolerance residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in milk, fat, meat, and meat byproducts for cattle, goats, hogs, horses, and sheep, and the proposed tolerances for poultry (meat, fat, and meat byproducts) will be assessed, and the adequacy of the available data regarding the magnitude of residues will be determined with consideration for any additional metabolites of toxicological concern.

74/ In light of the results of the Tolerance Assessment System (TAS) calculation, anticipated residue studies, i.e., processing, washing, cooking, baking, drying, etc., will be required for all of the commodities which the TAS has indicated make a significant contribution to the TMRC.

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA (c)(2)(B)?	Timeframes For Data Submission[3]/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,F,H	Yes	00143057	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes	9 months
161-3 - On soil	TGAI or PAIRA	A	Partial	00118525	Yes[4]/	4 months
161-4 - In Air	TGAI or PAIRA	A	No	-	Reserved 5/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,F,H	No	-	Yes	27 months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	7/14/88[3a]/
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No	-	No 6/	
162-4 - Aerobic Aquatic	TGAI or PAIRA		No	-	No 6/	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,F,H	Partial	00157196,00150930	Yes[7]/	12 months
163-2 - Volatility (Lab)	TEP	A,F	No	-	Yes	12 months
163-3 - Volatility (Field)	TEP	A,F	No	-	Reserved 8/	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA (c)(2)(B)?	Timeframes For Data Submission[3]
§158.130 Environmental Fate (continued)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No	-	Yes	27 months
164-2 - Aquatic (Sediment)	TEP	-	No	-	No [6]	
164-3 - Forestry	TEP	G	No	-	No [9]	
164-4 - Combination and Tank Mixes	TEP	-	No	-	No [6]	
164-5 - Soil, Long-term	TEP	A	No	-	Reserved [10]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes[11]	07/14/89[3a]
165-2 - Rotational Crops (Field)	TEP	A	No	-	Reserved [12]	
165-3 - Irrigated Crops	TEP	-	No	-	No [6]	
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	No[13]	
165-5 - In Aquatic Nontarget Organisms	TEP	-	No	-	No [6]	

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

§158.130 Environmental Fate (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; AEP = Applied end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop, F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise specified.

3a/ These data requirements were previously imposed as part of the Agency's 3(c)(2)(B) Call-In Notice of April 9, 1986. These submittal due dates reflect the timeframes imposed in that Call-In Notice.

4/ Additional information is required including: purity of the test substance, characterization of the artificial light source, and comparison of the light source with natural sunlight.

5/ Data may be required depending on the results of volatility studies.

6/ Data are not required to support current registered uses or are otherwise not applicable for this Standard.

7/ For the soil TLC studies submitted, additional information is needed on the purity of the test substance, the CEC of the soil, and Kd values. Additional batch equilibrium data (adsorption/desorption) are needed for three more soil types. Data on the leaching of oxydemeton-methyl soil degradation products in a sandy-loam soil are also needed.

8/ Data may be required depending on the results of the laboratory volatility studies.

9/ No data are required since tree injection treatments are not expected to significantly affect the forest environment.

10/ Data may be required depending on the results of field dissipation studies on terrestrial food crops and aerobic soil metabolism studies.

11/ No restriction on the planting of rotational crops in treated areas is being imposed since there are no data available at this time to form the basis of a specific restrictive interval. However, after the required data are received and evaluated a label restriction may be imposed if it is needed.

12/ Data may be required if significant residues of concern are found in the confined rotational crop study.

13/ Data are not required since the octanol/water partition coefficient is below 1000.

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition[1]/	Use Patterns[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data [3]/ Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A	Yes	00107024, 00110392	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00143350, 00107024	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	Yes	00151799, 00074085	No	
81-4 - Eye Irritation - Rabbit	TGAI	A	Yes	00151801	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A	Yes	00151801	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A	No	-	Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	No	-	Yes	12 Months
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding - Rodent	TGAI	A	Partially	00143351	Yes[5]/	15 Months
- Nonrodent	TGAI	A	No	-	Yes[6]/	18 Months
82-2 - 21-Day Dermal -	TGAI	A	No	-	Yes[7]/	12 Months
82-3 - 90-Day Dermal -	TGAI	A	No	-	No	
82-4 - 90-Day Inhalation -	TEP	A	No	-	No	
82-5 - 90-Day Neurotoxicity -	TGAI	A	No	-	Yes[8]/	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition[1]/	Use Patterns[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission [3]/
§158.135 Toxicology (cont'd)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent	TGAI	A	Partially	00151806	Yes[9]/	50 Months
Nonrodent	TGAI	A	Partially	00151805	Yes[9]/	50 Months
83-2 - Oncogenicity Study -						
Rat	TGAI	A	Partially	00151806	Yes[9]/	50 Months
Mouse	TGAI	A	Partially	00142617	Yes[9]/	50 Months
83-3 - Teratogenicity -						
Rat	TGAI	A	Yes	00146812, 00158342	No	
Rabbit	TGAI	A	Yes	00146989, 00153606	No	
83-4 - Reproduction	TGAI	A	Yes	00074114, 00074115	No	
MUTAGENICITY TESTING:						
84-2 - Gene Mutation	TGAI	A	Yes	00146101, 00146102	No	
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes[10]/	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	-	Yes[10]/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 3/ Submission
§158.135 Toxicology (cont'd)						
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA	A	No	-	Yes	24 Months
85-2 - Dermal Penetration	Choice	A	No	-	Reserved 4/	
85-3 - Domestic Animal Safety	Choice	A	No	-	Reserved 4/	
ADDITIONAL TESTING						
- Male Short Term Exposure Study	TGAI	A,B,G,H,F,I	No	-	Yes 11/	Oct. 31, 1988 13/14/
- Male Reproductive System Toxicity Study	TGAI	A,B,C,H,F,I	No	-	Yes 12/	Dec, 1987 13/15/ or Oct. 31, 1988

1/ Composition: TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop, F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.

3/ Due dates refer to the number of months following the registrant's receipt of the Registration Standard, unless otherwise specified.

4/ Reserved - not required at the present time.

5/ MRID 00143351 may be upgraded pending the submission of additional data. Not required if acceptable chronic data are available.

§158.135 Toxicology (cont'd)

6/ Not required if acceptable chronic data are available.

7/ Study classified as supplementary data; cannot be upgraded.

8/ Oxydemeton-methyl is an organophosphate, a subchronic neurotoxicity study is required if the acute study is positive.

9/ Study classified as supplementary data; may be upgraded pending the submission of additional data. However, new studies will be required if the issues are not satisfactorily resolved.

10/ Submitted data are unacceptable.

11/ Study is to examine the short-term effects of oxydemeton-methyl on the male reproductive system, and to address the question of reversibility. The study is to be conducted using the male Sprague Dawley rat, using the oral route of administration.

12/ This study is currently being conducted by Mobay, for the Calif. Dept. of Food and Agric., using the protocol entitled "Male Reproductive Toxicity in Rats with Metasystox-R® in the Diet", Protocol Number 86-671-01.

13/ This data requirement was previously imposed as part of the Agency's Call-in Notice of June 30, 1987. The submittal dates reflect the time frames imposed in the Call-in Notice.

14/ An interim progress report must be submitted to the Agency 2 months after the study is begun.

15/ A 3(c)(2)(B) Data Call-in was issued June 30, 1987. The submittal dates reflect the timeframes imposed in the DCI Notice. Interim progress reports must be submitted to the Agency in March, May, July (submitted), and September 1987. Three copies of the final report must be submitted to the Agency by December, 1987.

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON-METHYL

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA (c)(2)(B)?	Timeframes For Data Submission[3]
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,G	No	-	Yes[4]	27 months
132-2 - Soil Dissipation	TEP	A	No	-	Yes[5]	27 months
133-3 - Dermal Exposure	TEP	A,B,G	No	-	Conditional[6]	
133-4 - Inhalation Exposure	TEP	A,B,G	No	-	Conditional[6]	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	No	-	Yes[7]	27 months
202-1 - Drift Field Evaluation	TEP	A,B	No	-	Yes[7]	27 months

---

1. TEP = Typical end-use product.
2. The use patterns are coded as follows: A = Terrestrial Food Crop; B = Terrestrial Nonfood Crop; C = Aquatic Food Crop; D = Aquatic Nonfood; E = Greenhouse Food Crop; F = Greenhouse Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.
3. Due Dates refer to the number of months following the registrant's receipt of the Registration Standard, unless otherwise indicated.
4. For each end-use, the Registrant is required to propose an acceptable reentry interval based either upon data: (a) on dissipation of residues (decline curve), on human exposure to those residues, and on toxicity of the residues; or (b) on determination of that time beyond which there are detectable dislodgeable or inhalable residues remaining in the worker/occupant environment. If the Registrant has reasons to believe that an end-use will not cause exposure to residues, a request for waiver from this data requirement should be submitted.
5. Soil Dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work, e.g., for use on potatoes or peanuts where hand harvesting will be performed.
6. Human-exposure monitoring data may be submitted at the Registrant's option. If Dermal Exposure data are submitted, Inhalation Exposure data must also be submitted.
7. The spray drift droplet spectrum and drift field evaluation may be done together in order to evaluate the droplet spectra that are associated with actual field use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR OXYDEMETON METHYL

Data Requirement	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA (c)(2)(B)?	Timeframes For Data Submission[4]
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 Avian Acute Oral Toxicity	TGAI	A,B,F,G,H	Yes	00060636 00160000 [3]/	No	
71-2 Avian Subacute Dietary	TGAI	A,B,G,H,[F,I][6]/	Yes	00022923	No	
71-3 Wild Mammal Toxicity	TGAI	A,B,G,H	No	-	No	
71-4 Avian Reproduction	TGAI	A,G	No	-	Yes[7]/	04/14/88[5]/
71-5 Simulated and Actual Field Testing for Mammals and Birds	TEP	A	No	-	No	
AQUATIC ORGANISMS TESTING						
72-1 Freshwater Fish Toxicity						
- Coldwater	TGAI	A,B,G,H,[F,I][8]/	Yes	40094602 40269001	No	
- Warmwater	TGAI	A,B,G,H	Yes	40094602 00060639 40269002	No	
72-2 Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,G,H,[F,I][8]/	No	-	Yes	9 months
72-3 Acute Toxicity to Estuarine and Marine Organisms	TGAI	A	No	-	Reserved[9]/	

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TABLE A

GENERIC DATA REQUIREMENTS FOR OXYDEMETON METHYL (cont'd)

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA (c)(2)(B)?	Timeframes For Data Submission[4]
§158.145 Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISMS TESTING (cont'd)						
72-4 Fish Early Life-Stage and Aquatic Invertebrate Life Cycle						
- Freshwater fish	TGAI	A	No	-	Yes	15 months
- Invertebrate	TGAI	A	No	-	Yes	15 months
72-5 Fish Life Cycle	TGAI	A	No	-	No	
72-6 Aquatic Organism Accumulation	TGAI	A	No	-	Yes[7]	27 months
72-7 Simulated or Actual Field Testing for Aquatic Organisms	TEP	A	No	-	Reserved[8]	

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[1] Composition of the material to be tested is technical grade unless otherwise specified in footnotes.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

[3] All the studies collectively satisfy the data requirement and must be cited together.

[4] Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise specified.

[5] These data requirements were previously imposed as part of the Agency's 3(c)(2)(B) Call-In Notice of April 9, 1986. These submittal due dates reflect the timeframes imposed in that Call-In Notice.

§158.145 Wildlife and Aquatic Organisms (cont'd)

6/ Testing is required with only one avian species. The testing is required to support the manufacturing use product for reformulation in these end-use products.

7/ The avian reproduction studies are needed to support the uses of crops with multiple applications such as cotton, alfalfa, grapes, and sugar beets.

8/ The testing is required to support the manufacturing-use product for reformulation into these end-use products (F,I).

9/ The use of oxydemeton methyl in coastal areas is relatively small. Since the chemical is not expected to be transported to estuarine waters in significant concentrations, acute toxicity testing of estuarine organisms is not presently needed. If new data indicate that the pesticide can enter estuarine waters in significant concentrations, these studies may be required.

10/ Refer to LAB chapter for details of this data requirement.

11/ The field study is reserved pending receipt of the environmental fate data and the aquatic organism toxicity tests.

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TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING OXYDEMETON-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP3/	All	1/	1/	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	1/	1/	Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	1/	1/	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	1/	1/	Yes	12 Months
62-2 - Certification of Limits	MP	All	1/	1/	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	1/	1/	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	1/	1/	Yes	6 Months
63-3 - Physical State	MP	All	1/	1/	Yes	6 Months
63-4 - Odor	MP	All	1/	1/	Yes	6 Months
63-6 - Boiling Point	MP	All	1/	1/	Yes	6 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING OXYDEMETON-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	1/	1/	Yes	6 Months
63-8 - Solubility	MP	All	1/	1/	Yes	6 Months
63-9 - Vapor Pressure	MP	All	1/	1/	Yes	6 Months
63-10 - Dissociation Constant	MP	All	1/	1/	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	MP	All	1/	1/	Yes	6 Months
63-12 - pH	MP	All	1/	1/	Yes	6 Months
63-13 - Stability	MP	All	1/	1/	Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	1/	1/	Yes	6 Months
63-15 - Flammability	MP	All	1/	1/	Yes	6 Months
63-16 - Explodability	MP	All	1/	1/	Yes	6 Months
63-17 - Storage Stability	MP	All	1/	1/	Yes	15 Months (8 Months - Progress Report)

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING OXYDEMETON-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-18 - Viscosity	MP	All	1/	1/	Yes	6 Months
63-19 - Miscibility	MP	All	1/	1/	Yes	6 Months
63-20 - Corrosion Characteristics	MP	All	1/	1/	Yes	6 Months
Other Requirements						
64-1 - Submittal of Samples	MP	All	-	-	Reserved4/	

Footnotes

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

3/ Formulation intermediates are also included in the category of manufacturing-use products.

4/ If samples are needed, the Agency will request them.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING OXYDEMETON-METHYL

Data Requirement	Composition[1]	Use Patterns[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[3]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	MP	All	[4]	-	Yes[5]	9 Months
81-2 - Acute Dermal -	MP	All	[4]	-	Yes[5]	9 Months
81-3 - Acute Inhalation - Rat	MP	All	[4]	-	Yes[5]	9 Months
81-4 - Eye Irritation - Rabbit	MP	All	[4]	-	Yes[5]	9 Months
81-5 - Dermal Irritation - Rabbit	MP	All	[4]	-	Yes[5]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	[4]	-	Yes[5]	9 Months

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[1] Composition: TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop, F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor; IP = Industrial Preservative.

[3] Due dates refer to the number of months following the registrant's receipt of the Registration Standard, unless otherwis specified.

[4] Although product specific toxicity data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product.

[5] If the MP is a technical grade active ingredient, refer to the Toxicology Table A for data requirements which may have been satisfied.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

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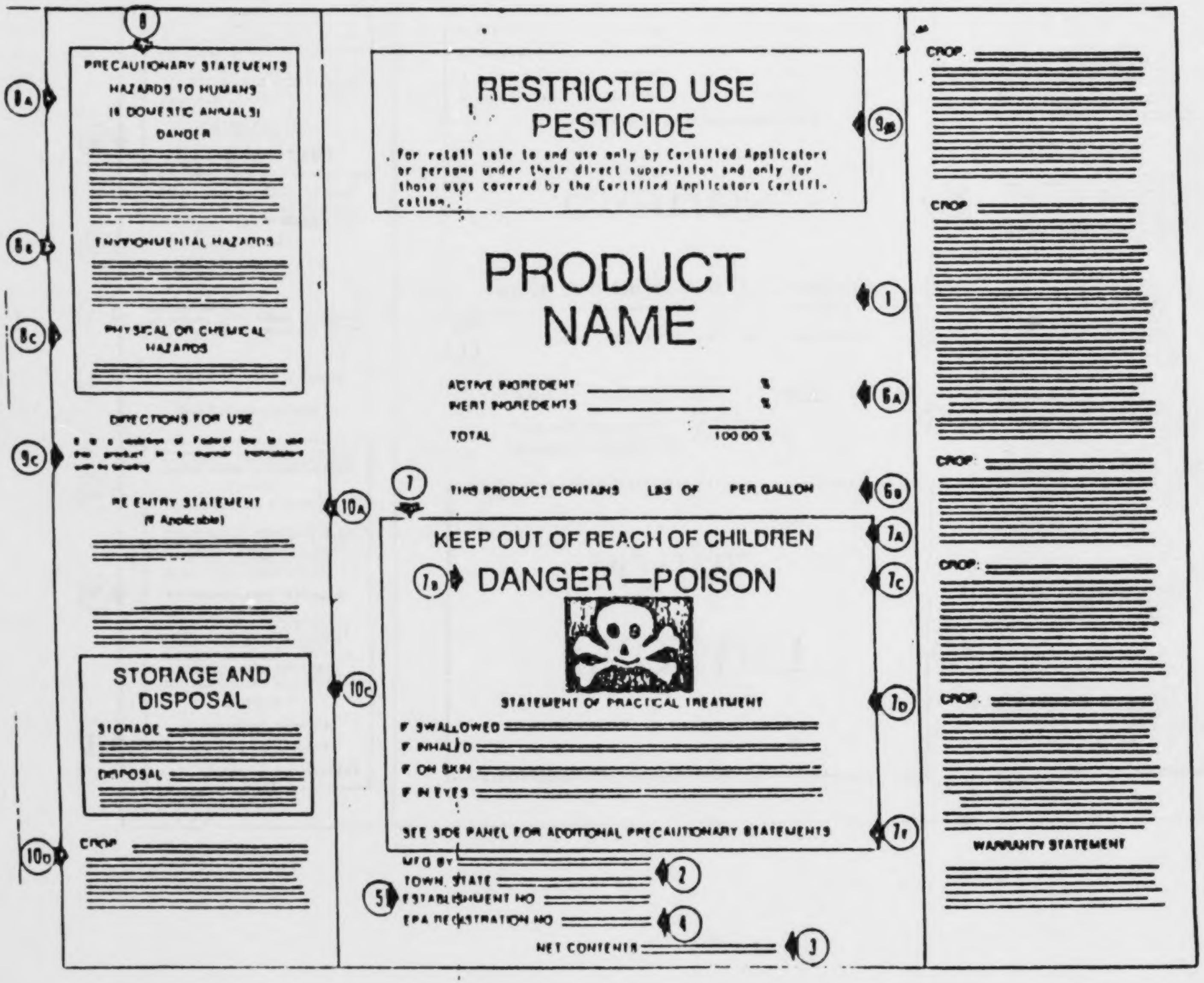
SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
RE ENTRY STATEMENT
(If Applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
CROP
RESTRICTED USE PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.
PRODUCT NAME
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL 100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
DANGER —POISON
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS
CROP:
CROP:
CROP:
CROP:
CROP:
WARRANTY STATEMENT
8
8A
8B
8C
9C
10D
10A
10C
7
7A
7B
7C
7D
7F
9B
1
6A
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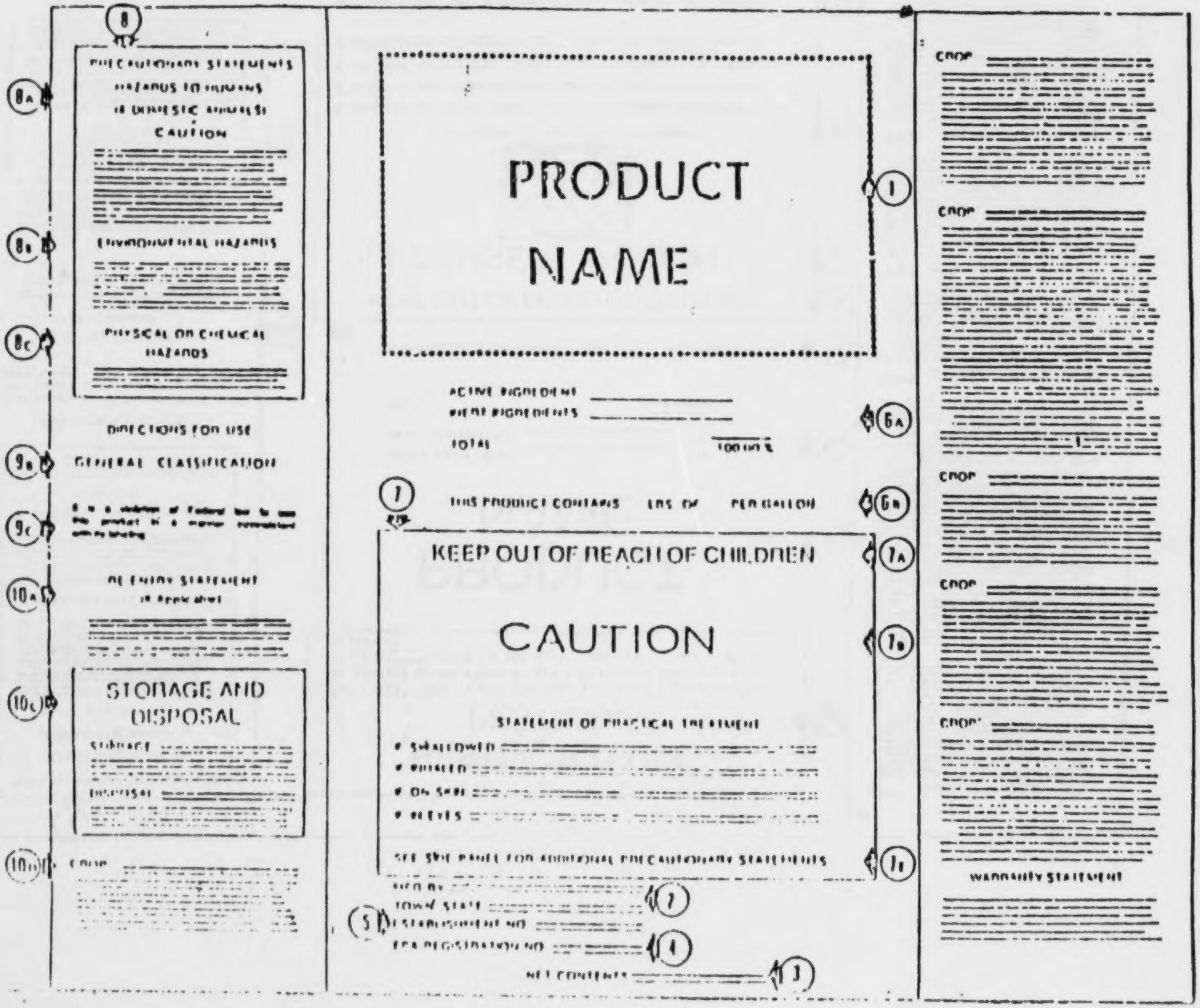
8
8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
9B
GENERAL CLASSIFICATION
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
10A
RE-ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
10D
CROP
PRODUCT NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00%
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7C
MFD BY
TOWN, STATE
2
5
ESTABLISHMENT NO.
EPA REGISTRATION NO.
4
NET CONTENTS
3
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

~~(e) *Conditional registration.* Any application for which a review of scientific data is needed, other than an application which the Agency determines may be considered for unconditional registration under paragraph (d) of this section, will be treated as an application for conditional registration under FIFRA sec. 3(c)(7) and will be reviewed and acted upon as set forth in §§ 162.160 through 162.177.~~

~~(f) *Denial of registration.* The Administrator shall deny an application reviewed under paragraph (d) of this section if any of the requirements of paragraph (d)(2) of this section are not met, or if there are insufficient data to make the required determinations.~~

~~(1) *Notification.* Promptly after making a determination to deny a registration, the Administrator shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.~~

~~(2) *Opportunity for remedy by applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.~~

~~(ii) The applicant may petition the Administrator to withdraw his application. The Administrator may, in his discretion, deny any petition for withdrawal and proceed to issue a notice of denial in accordance with paragraph (f)(3) of this section.~~

~~(3) *FEDERAL REGISTER publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly issue in the FEDERAL REGISTER a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.~~

~~(4) *Hearing rights.* Within 30 days following publication of the denial in the FEDERAL REGISTER, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of this chapter. If no hearing is timely requested, the denial shall become effective at the end of the 30 days.~~

~~(g) *Disposition of material submitted with the application.* The test data and other information submitted with an application shall become a part of the official file of the Agency for that application or registration. Except as provided by section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.~~

~~[48 FR 34004, July 28, 1983]~~

~~**§ 162.8 Data to be furnished by applicant.**~~

~~(a) An applicant for registration, reregistration, or amendment of a registration under FIFRA sec. 3(c)(5) shall furnish data as required by the Agency to determine whether his application may be approved under this Part.~~

~~(b) An applicant shall submit with his application any factual information regarding adverse effects of the pesticide on the environment or man that:~~

~~(1) Has been obtained by him or has come to his attention; and~~

~~(2) Insofar as he is aware, has not previously been submitted to the Agency.~~

~~Such information shall include, but shall not be limited to, published or unpublished laboratory studies and accident experience.~~

~~[48 FR 34005, July 26, 1983]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC$_{50}$	Up to and including 2 mg/liter	From 2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes. on skin, or on clothing. Harmful if swallowend [Appropriate first aid statement required.]
III	Harmful if swallowend [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a)-(b) [Reserved]~~

~~(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.~~

~~(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:~~

~~(A) Has an acute dermal LD$_{50}$ greater than 2,000 mg/kg;~~

~~(B) Has an inhalation LC$_{50}$ greater than 2 mg/liter;~~

~~(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;~~

~~(D) Causes no more than moderate skin irritation within 72 hours;~~

~~(E) Has an acute oral LD$_{50}$ greater than 1.5 g/kg for the formulation as diluted for use; and~~

~~(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).~~

~~(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:~~

~~(A) Has an acute dermal LD$_{50}$ greater than 200 mg/kg;~~

~~(B) Has an acute dermal LD$_{50}$ greater than 16 g/kg for the formulation as diluted for use as a mist or spray;~~

~~(C) Has an inhalation LD$_{50}$ greater than 0.2 mg/liter;~~

~~(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days;~~

~~(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and~~

~~(F) Causes under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their their metabolite(s), or degradation product(s).~~

~~(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:~~

~~(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the acute oral LD$_{50}$, measured in mammalian test animals as specified in the Registration Guidelines.~~

~~(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the subacute dietary LC$_{50}$ measured in avian test animals as specified in the Registration Guidelines.~~

~~(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $\frac{1}{10}$ the acute LC$_{50}$ for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.~~

~~(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.~~

~~(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has sub-~~

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX APPENDIX

EPA Index to Pesticide Chemicals

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

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S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

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c058702 S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE*

__TYPE PESTICIDE__: Insecticide, Acaricide

__FORMULATIONS__:

Fl (0.5 lb/gal, 25%, 50%)

P/T (50%)

EC (0.25 lb/gal, 0.48 lb/gal, 0.5 lb/gal, 1 lb/gal, 2 lb/gal, 4 lb/gal, 2%, 2.45%, 2.5%, 5%, 5.6%, 6%, 6.25%, 7.5%, 11.74%, 13.5%)

SC/L (5.6%, 6%)

PrL (0.25%, 0.4%)

__GENERAL WARNINGS AND LIMITATIONS__: Refer to appropriate labeling for ENDANGERED SPECIES RESTRICTIONS. Labeling for products with danger and warning signal words: Handle the concentrate only when wearing the following protective clothing and equipment: Wear a protective suit of 1 or 2 pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield and a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II. During application from an enclosed tractor cab or airplane cockpit, or other suitable vehicle in which the windows are rolled up, long sleeved shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. This clothing is inadequate for protection during equipment repair, equipment cleaning, reentry, or during pesticide disposal.

Agricultural Safety Label Language for Dermal or Oral Toxicity III Formulations of Oxydemeton-Methyl: Handle the concentrate only when wearing the following protective clothing and equipment. Wear long sleeve shirt and long legged pants. Wear chemical resistant gloves. Wear the following protective clothing during application, equipment repair, equipment cleaning, disposal of the spray solution, or reentry to treated areas prior to the expiration of the reentry interval. Wear long sleeve shirt and long legged pants. During aerial application, human flaggers must be in totally enclosed vehicles. Home Use Safety Label Language for Dermal or Oral Toxicity III Formulations of Oxydemeton-Methyl: Handle this product only when wearing long sleeve shirt, long pants, and chemical resistant gloves.

__Bee Caution__: Oxydemeton-methyl is toxic to bees exposed to direct treatment. Do not apply oxydemeton-methyl while bees are actively visiting the treatment area.

__Agricultural Tolerances__ (other than those listed in the text):

Sorghum, milled fractions (except flour) - 2.0 ppm

__Livestock Tolerances__:

Cattle, fat	0.01 ppm
Cattle, meat	0.01 ppm
Cattle, mbyp	0.01 ppm

*Metasystox-R

Oxydemeton-methyl

O-O dimethyl S-[2-(ethylsulfinyl)ethyl] phosphorothioate

GENERAL WARNINGS AND LIMITATIONS (continued)

Goats, fat	0.01 ppm
Goats, meat	0.01 ppm
Goats, mbyp	0.01 ppm
Horses, fat	0.01 ppm
Horses, meat	0.01 ppm
Horses, mbyp	0.01 ppm
Hogs, fat	0.01 ppm
Hogs, meat	0.01 ppm
Hogs, mbyp	0.01 ppm
Milk	0.01 ppm
Sheep, fat	0.01 ppm
Sheep, meat	0.01 ppm
Sheep, mbyp	0.01 ppm

Definition of Terms:

MAI - multiple active ingredient(s)

** - Computed from tablespoons/teaspoons dosage.

Claims for pest control limited to suppression of population are indicated by an entirely parenthesized pest name.

DBH - diameter at breast height

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/23001BA	Alfalfa (seed)		11 ppm (hay for seed) No preharvest interval through 0.5 pound per acre for foliar application.
/23003BA	Clover (seed)		
IRACAAA	Aphids	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage but not less than 1 gallon per acre. Repeat as necessary. Do not graze or use treated crop for feed, food or forage.
IRAFAAA	Leafhoppers		
ILAAABA	Mites		
IMDAAAA	Thrips		

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04001DA /05001DA /05002DA /04002DA /01014DA /05003DA /04004DA /05004DA	Apple (nonbearing) Apricot (nonbearing) Cherry (nonbearing) Crabapple (nonbearing) Grapes (nonbearing) Nectarine (nonbearing) Quince (nonbearing)		N.F. Do not apply to trees or vines which will bear fruit in the next 12 months.
IRACAAA ILAAABA	Aphids Mites	0.25-0.375 lb/100 gal (2 lb/gal EC) 003125-00111	Foliar application. Repeat as needed.
	Apricot (nonbearing)		See Apple (nonbearing) cluster.
/06001DA	Avocado (nonbearing)		N.F. Do not apply to trees which will bear fruit in the next 12 months.
IRACAAA	Aphids	[SLN] 0.0625 oz/gal (2 lb/gal EC)	SLN - Use limited to CA. Foliar application. Repeat as necessary.
/01002AA /01006AA	Blackberry Raspberry		2 ppm 7 day preharvest interval through 0.375 pound per 100 gallons for foliar application. Do not make more than 1 application per season.
IRACAAA ILAAABA	Aphids Mites	0.25-0.375 lb/100 gal (2 lb/gal EC) 000070-00241	Foliar application.
/28066BA	Bluegrass (seed crop)		Do not graze livestock or use treated crop for feed, food, forage or bedding.
IMOAAAA	Thrips	[SLN] 1 lb/A (2 lb/gal EC)	SLN - Use limited to ID, OR, and WA. Foliar application. Apply in sufficient water for thorough coverage but not less than 1 gallon per acre. Repeat as necessary.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13005AA	Broccoli		1 ppm 21 day preharvest interval through 0.5 pound per gallon for foliar application. Do not make more than 1 application per season.
IRACAAA	Aphids	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111 [MAI] 0.06 oz/gal (6% EC)**	Foliar application. May be applied by aircraft. Apply in sufficient water for thorough coverage. May be formulated with trichlorfon.
/13006AA /13007AA /13008AA	Brussels Sprouts Cabbage Cauliflower		1 ppm 24 day preharvest interval through 0.5 pound per gallon for foliar application. Do not make more than 3 applications per season.
IRACAAA	Aphids	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111 [MAI] 0.06 oz/gal (6% EC)**	Foliar application. May be applied by aircraft. Apply in sufficient water for thorough coverage. May be formulated with trichlorfon.
	Cabbage		See Brussels Sprouts cluster.
	Cauliflower		See Brussels Sprouts cluster.
	Cherry (nonbearing)		See Apple (nonbearing) cluster.
/02000DA	Citrus (nonbearing)		N.F. Do not apply to trees which will bear fruit in the next 12 months.
IRACAAA ILAVAKA	Aphids Texas citrus mite	0.25-0.375 lb/100 gal (2 lb/gal EC) 003125-00111	Foliar application. Repeat as needed.
	Clover (seed)		See Alfalfa (seed) cluster.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28005AA	Corn		0.5 ppm (fresh, grain [including sweet (K+CWHR)]) 3.0 ppm (fodder, forage) 14 day preharvest interval (grain); or 30 day preharvest interval (fodder) through 0.5 pound per acre for foliar application. Do not make more than 1 application per season.
IRAFAAA ILAAABA IMDAAAA	Leafhoppers Mites Thrips	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111 [MAI] 0.06 oz/gal (6% EC) 007401-00420	Foliar application. Apply in sufficient water for thorough coverage. May be formulated with trichlorfon.
IRACAAA ILAAABA IRAFAAA ILAAABA IMDAAAA	Aphids Corn rootworm (adult) Leafhoppers Mites Thrips	[SLN] 0.375-0.5 lb/A (2 lb/gal EC)	SLN - Use limited to KS, NM, TX, and UT. Foliar application. May be applied by aircraft. May be tank mixed with carbofuran.
/28007AA	Cotton		0.1 ppm (cotton seed) 14 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 3 applications per season. Do not graze or feed gin trash to meat or dairy animals.
IRACAAA ILAAABA	Aphids Mites	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage but not less than 1 gallon per acre.
	Crabapple (nonbearing)		See Apple (nonbearing) cluster.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/10010AA	Cucumber		1 ppm 14 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 2 applications per season.
IRACAAA ILAAABA	Aphids Mites	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage but not less than 1 gallon per acre.
/11001AA	Eggplant		1 ppm 7 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 3 applications per season.
IRACAAA ILAAABA	Aphids Mites	0.5 lb/A (2 lb/gal EC) 000070-00241	Foliar application. Apply in sufficient water for thorough application.
/03005AA	Filbert		0.05 ppm 105 day preharvest interval (bark treatment) through 0.0825 ounce per inch of trunk diameter. 116 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 1 application per season.
IRACAAA	Aphids	0.0825 oz/in. of trunk diameter (DBH) (2 lb/gal EC) 000070-00241	Bark treatment. May be diluted with equal volume of water or applied undiluted with brush or low pressure sprayer in a band completely around the trunk. On trees with extremely short trunks it may be necessary to treat bases of scaffold limbs to ensure correct dosage. Width of treated band varies with trunk diameter. Do not use on heavily stressed trees or on trees of less than 2 inch trunk diameter.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Filbert (continued)		
IRACCPA	Filbert aphid	[SLN] 0.5 lb/A (2 lb/gal EC)	SLN - Use limited to OR and WA. Foliar application. Apply in sufficient water for thorough coverage. Do not graze or feed cover crops.
/02002AA /02004AA /02006AA	Grapefruit Lemon Orange		1 ppm 7 day preharvest interval through 0.375 pound per 100 gallons for foliar application. Do not make more than 2 applications per season.
IRACAAA ILAVAKA	Aphids Texas citrus mite	0.25-0.375 lb/100 gal (2 lb/gal EC) 000070-00241	Foliar application.
/01014AA	Grapes		0.1 ppm 90 day preharvest interval through 0.375 pound per 100 gallons per acre for foliar application. Do not make more than 2 applications per season.
IRACAAA IRAFAAA ILAAABA	Aphids Leafhoppers Mites	0.25-0.375 lb/100 gal/A (2 lb/gal EC) 000070-00241	Foliar application.
	Grapes (nonbearing)		See Apple (nonbearing) cluster).
	Lemon		See Grapefruit cluster.
/13020AA	Lettuce (head)		2 ppm 21 day preharvest interval through 0.5 pound per acre for foliar application (28 day for CA and AZ). Do not make more than 3 applications per season.
IRACAAA ILAAABA	Aphids Mites	0.375-0.5 lb/A (2 lb/gal EC) 000070-00241 or	Foliar application. May be applied until heads form. May be formulated with trichlorfon.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Lettuce (head) (continued)		
		[MAI] 0.06 oz/gal (6% EC)**	
/15025AA /15003AA	Lima Beans Snap Beans		0.5 ppm (fresh) 2.0 ppm (forage) 21 day preharvest/pregrazing interval through 0.5 pound per acre for foliar application. Do not make more than 3 applications per season.
IRACAAA IRAFAAA IQAMARA ILAAABA	Aphids Leafhopper Lygus bug Mites	0.5 lb/A (2 lb/gal EC) 000070-00241	Foliar application. For lygus bug in CA. May be formulated with trichlorfon.
		[MAI] 0.0625 oz/gal (6% EC)**	
/28012AA	Mint (including spearmint and peppermint)		12.5 ppm (hay) 14 day preharvest interval through 0.75 pound per acre for foliar application.
IRACAAA ILAAABA	Aphids Mites	0.75 lb/A (2 lb/gal EC) 000070-00241	Foliar application. Apply when insects or damage are first observed and repeat in 10 to 14 days if necessary.
/10006AA /10008AA	Muskmelon Watermelon		0.3 ppm 7 day preharvest interval for watermelon and 14 day preharvest interval for muskmelons through 0.5 pound per acre for foliar application. Do not make more than 2 applications per season for watermelon or more than 3 applications per season for musmelon.
IRACAAA ILAAABA	Aphids Mites	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage, but not less than 1 gallon per acre.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Muskmelon cluster (continued)		
IRAFAAA	Leafhoppers	[SLN] 0.5 lb/A (2 lb/gal EC)	SLN - Use limited to CA. Foliar application. Apply by aircraft at vining stage.
	Nectarine (nonbearing)		See Apple (nonbearing) cluster.
/14011AA	Onion (Spanish dry bulb)		0.05 ppm 30 day preharvest interval through 0.75 pound per acre for foliar application.
IMOAAAA	Thrips	0.75 lb/A (2 lb/gal EC) 000070-00241	Use limited to the western United States. Foliar application. Apply in sufficient water for thorough coverage. Make 3 applications at 10 to 14 day intervals when damage becomes apparent.
	Orange		See Grapefruit cluster.
/05004DA	Peach (nonbearing)		N.F. Do not apply to trees which will bear frut in the next 12 months.
IRACCUA	Green peach aphid	[SLN] 0.125-0.25 oz/in. of trunk diameter (DBH) (2 lb/gal EC)	SLN - Use limited to ID, OR, and WA. Soil drench. Apply in 0.5 to 1 gallon of water per inch of trunk diameter (DBH). Apply at bud swell, prior to leaf or blossom development. Soil should be prepared so that there is no runoff of material beyond drip line. Grass or cover crops in treated areas should not be grazed or clippings used as feed. Keep children and pets off treated areas until drench has soaked into soil.

Refer to Apple (nonbearing) cluster for additional use and dose information.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04003AA	Pear		0.3 ppm 30 day preharvest interval through 0.25 pound per 100 gallons for foliar application. Do not make more than 1 application per season.
IRACAAA ILAAABA	Aphids Mites	0.25 lb/100 gal (2 lb/gal EC) 000070-00241	Foliar application.
/28016AA	Peas		2 ppm (forage) 3 ppm (peas) 8 ppm (hay) 21 day preharvest interval through 0.375 pound per acre for foliar application. Do not make more than 3 applications per season.
IRACAAA	Aphids	0.375 lb/A (2 lb/gal EC) 000070-00241	Use limited to the north central United States. Foliar application. Apply in sufficient water for thorough coverage.
/03008DA /03008DA	Pecan (nonbearing) Walnut (nonbearing)		
IRACAAA ILAAABA	Aphids Mites	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Use limited to professional pest control operators. Injection application. Do not inject trees less than 2 inches in diameter (DBH). Do not inject trees within 2 weeks of any other treatment. Do not apply to trees suffering from stress. Do not apply to trees which will produce fruit within the next 12 months. For aphids, apply when wingless forms appear. For mites, apply after eggs hatch.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28017AA	Peppers		0.75 ppm 21 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 2 applications per season.
IRACAAA ILAAABA IMOAAAA	Aphids Mites Thrips	0.5 lb/A (2 lb/gal EC) 000070-00241 [MAI] 0.625 oz/gal (6% EC)**	Foliar application. Apply in sufficient water for thorough coverage. May be formulated with trichlorfon.
IRAFAAA	Leafhoppers	[SLN] 0.5 lb/A (2 lb/gal EC)	SLN - Use limited to CA. Foliar application. Apply by aircraft after the crop is established.
/05005AA /05006AA	Plum Prune		1 ppm 35 day preharvest interval through 0.25 pound per 100 gallons for foliar application. Do not make more than 2 applications per season.
IRACAAA ILAAABA	Aphids Mites	0.25 lb/100 gal (2 lb/gal EC) 000070-00241	Foliar application.
/14031AA	Potato		0.1 ppm 7 day preharvest interval through 0.5 pound per acre for foliar application.
IRACAAA INAMADA IRAFAAA	Aphids Flea beetle Leafhoppers	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage in not less than 1 gallon per acre. Repeat as necessary.
	Prune		See Plum cluster.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/10011AA /10013AA /10014AA	Pumpkin Summer Squash Winter Squash		0.3 ppm (pumpkin, winter squash) 1.0 ppm (summer squash) 14 day preharvest interval (pumpkin, winter squash) and 1 day preharvest interval (summer squash) through 0.5 pound per acre for foliar application. Do not make more than 1 application per season.
IRACAAA	Aphids	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage.
	Quince (nonbearing)		See Apple (nonbearing) cluster.
	Raspberry		See Blackberry cluster.
	Snap Beans		See Lima Beans cluster.
/28019AA	Sorghum		0.75 ppm (grain) 2.0 ppm (forage) 45 day preharvest interval through 0.5 pound per acre for foliar application. 21 day pregrazing interval or precutting (forage) interval. Do not make more than 3 applications per season. Do not apply to sweet sorghum.
ILAVANA IRAKDKA IRACDNA	Banks grass mite Corn leaf aphid Greenbug	0.25-0.5 lb/A (4 lb/gal EC) 003125-00312	Use limited to the southwest including AZ, CO, KS, OK, NM, and TX. Foliar application. Apply in sufficient water for thorough coverage. For mites, apply at the higher rate. Apply in not less than 1 gallon per acre water by aircraft or ground.
IRACDOA	Yellow sugarcane aphid	[SLN] 0.25-0.5 lb/A (2 lb/gal EC)	SLN - Use limited to TX. Foliar application. May be applied by aircraft.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01016AA	Strawberry		2 ppm 3 day preharvest interval through 0.75 pound per acre for foliar application. Do not make more than 2 applications per season.
IRACAAA ILAAABA	Aphids Mites	0.375-0.75 lb/A (2 lb/gal EC) 000070-00241	Foliar application. Apply in sufficient water for thorough coverage.
IRACBGA	Strawberry aphid	[SLN] 0.5 lb/A (2 lb/gal EC)	SLN - Use limited to WA. Foliar application. May be applied by aircraft. May be applied once after harvest.
/15002AA	Sugar Beets		0.3 ppm (if tops are not to be used as food or feed) 0.5 ppm (if tops are to be used as food or feed) 30 day preharvest interval through 0.5 pound per acre for foliar application. Do not make more than 2 applications per season.
IRACAAA IRAFAAA ILAAABA	Aphids Leafhoppers Mites	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage but not less than 1 gallon per acre.
	Summer Squash		See Pumpkin cluster.
/28022AA	Turnips		0.3 ppm 2.0 ppm (tops) 21 day preharvest interval if tops are to be used as food or feed (7 day preharvest interval if tops are not to be used) through 0.5 pound per acre for foliar application. Do not make more than 1 application per season.
IRACAAA ILAAABA	Aphids Mites	0.375-0.5 lb/A (2 lb/gal EC) 003125-00111	Foliar application. Apply in sufficient water for thorough coverage, but not less than 1 gallon per acre.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/03009AA	Walnut		0.03 ppm 30 day preharvest interval through 0.375 pound per 100 gallons for foliar application.
IRACAAA ILAAABA	Aphids Mites	0.375 lb/100 gal (2 lb/gal EC) 000070-00241	Foliar application.
	Walnut (nonbearing)		See Pecan (nonbearing) cluster.
	Watermelon		See Muskmelon cluster.
	Winter Squash		See Pumpkin cluster.

TERRESTRIAL NONFOOD CROP

(Ornamental Plants and Forest Trees)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/35157AA	Christmas Tree Plantations		
IRACAAA	Aphids (including spotted pine aphid)	[SLN] 0.25-0.75 lb/A (2 lb/gal EC)	SLN - Use limited to OH. Foliar application. Apply by aircraft. Apply in 2 to 5 gallons of water per acre. Use higher rate in dense trees with high insect populations. Apply in early May in northern OH and 3 weeks earlier in southern OH.
/31003AA /32001AA /31003FA	Ornamental Flowering Plants Ornamental Woody Plants		Do not apply to certain chrysanthemum or Easter Lily varieties as injury may result to plants.
IRACAAA IRAFAAA IMAAAGA IQAMARA ILAAABA IMOAAAA IRABAAA	Aphids Leafhoppers Leafminers (including birch leafminer, dipterous leafminer, and holly leafminer) Lygus bug Mites Thrips Whiteflies	0.3125-0.072 oz/gal (0.5-2 lb/gal EC) 001386-00487 (2%, 2.45%, 13.5% EC)** 001266-00088 or	Foliar application. Cover all surfaces. Avoid application at temperatures above 85 F (29.4 C). Do not apply to drought stressed plants. Repeat as necessary. May be formulated with one or more of the following: carbaryl, trichlorfon, folpet, dinocap, dicofol, or methoxychlor.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Ornamental Flowering Plants cluster (continued)		
		[MAI] 0.033-0.125 oz/gal (0.25 lb/gal, 0.5 lb/gal EC) (2.5-11.74% EC)** (5.6%, 6% SC/L) or -- (0.25%, 0.4% PrL)	
IRAFAAA IMAAAGA IRABAAA	Leafminers Leafminers Whiteflies	approximately 0.08 oz/gal (0.48 lb/gal EC) 005719-00065	Soil application. Apply 0.25 pint of solution per 6 to 8 inch diameter pot. Repeat as necessary.
IRAAABA	Scales	[SLN] 0.375-0.5 lb/100 gal (2 lb/gal EC)	SLN - Use limited to FL. Foliar application.
/31003DA	Ornamental Flowering Plants and Trees (including chrysanthemum, cuban laurel, dahlia, and roses		
IRACAAA ILAAABA IMDAAAA	Aphids Mites Thrips (including cuban laurel thrips)	0.02-0.0625 oz/gal (2 lb/gal EC) 002749-00198	Soil drench. Mix specified dose in 50 gallons of water to form an emulsion. For indoor plants or plants in containers, apply 1 quart of emulsion per 5 gallons of container capacity or 4 fluid ounces per 6 to 8 inch diameter container. For established trees (outdoor), use 4 gallons of emulsion per inch of trunk diameter (DBH).

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S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIDATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/33010AA	Ornamental Lawns and Turf		Keep children and pets off treated areas until dry.
ILAVABA	Clover mite	[MAI] 0.0625 oz/gal (6% EC)**	Foliar application. Water thoroughly after application. Formulated with methoxychlor or dicofol.
/32000DA	Ornamental Nursery Stock		
IRACAAA	Aphids	[SLN] 0.0625-0.0825 oz/in. trunk diameter (DBH) (2 lb/gal EC)	SLN - Use limited to ID, OR, UT, and WA. Soil injection. Inject 4 to 6 inches below soil surface. Moisten soil prior to application. Make 2 injections per inch of trunk diameter at breast height (DBH). Soil drench. Use in commercial nurseries only. Dilute with equal volume of water, pour around base of tree and allow to soak in. Water for 12 to 24 hours after application.
	GREENHOUSE NONFOOD CROP		
	(Agricultural Crops)		
/28037CA	Research Crops (not for consumption)		For use only in greenhouses of Del Monte Corporation. Crops (including resulting products) must be destroyed following harvest and in no case be consumed.
IRACAAA ILAAABA IMOAAAA IRABAAA	Aphids Mites Thrips Whiteflies	[SLN] 1 oz/19.69 gal (2 lb/gal EC)	SLN - Use limited to CA. Foliar application. Use handheld spray wand. Apply to runoff. Repeat as necessary.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	DOMESTIC OUTDOOR		
	(Household)		
/63003DA	Domestic Dwellings, Outdoor		Do not apply to patio surfaces. Do not allow children and pets onto treated surfaces until dry.
ISASAAA IQAUACA IKACABA IVAHAAA IMDAAAA ILAAABA IIFAAEA	Ants Boxelder bugs Black widow spider Crickets Earwigs Mites (including brown mite, brown almond mite, and clover mite) Sowbugs	[MAI] 0.937 oz/gal (5% EC) or 0.072-0.937 oz/gal (6% EC)	Outdoor residual treatment. Apply around building foundations and along fences, shrubbery areas and other infested areas. Repeat as necessary. Formulated with carbaryl, dicofol, or methoxychlor.
	FORESTRY		
	(Ornamental Plants and Forest Trees)		
	General Warnings and Limitations: Injection treatments are limited to professional pest control operators. Do not inject trees less than 2 inches in diameter. Allow 14 days between any other treatments. Do not apply to trees suffering from stress.		
/30037AA /30073AA	Cedar Juniper		
INBQAAA	Bark beetles	1 unit/4-6 in. around the trunk at base of tree (50% P/T) 007946-00001	Injection treatment. Apply from early spring through October. Repeat after new infestations.
/30133AA	Cottonwoods		
IRACAAA	Aphids	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. Apply when wingless forms appear.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/30042AA	Cypress		
INBDAAA	Bark beetles	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. For bark beetles, apply from spring through October. Repeat after new infestations. For mites, apply after eggs hatch.
ILAAABA	Mites		
/30044AA	Douglas Fir		
ITAAADA	Cone moths	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. For cone moths, apply to heavy cone crop trees during or shortly after eggs are deposited. For engraver beetle, apply from spring through October. Repeat after new infestation.
IZZZAIA	Engraver beetles		
/35044BA	Douglas-Fir Seed and Breeding Orchards		
IDAHBFA	Cone moths	[SLN] 6.25-8.25 lb/A (2 lb/gal EC)	SLN - Use limited to WA. Foliar application. Apply in 100 to 200 gallons of water. Spray foliage thoroughly to cover foliage and conelets. Apply after conlet closure and while conlets are turning down. Repeat as necessary.
ITAAADA	Coneworms		
IDAHBGA	Contarina gall midge		
	Megastigmus calcids		
ITBIAAA	Phaloniids		
/30049AA	Elms		
INAMDAA	Elm leaf beetle	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. Apply after eggs are present or during early larval feeding.

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S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/30098AA	Pines (excluding Pinyon Pine)		
INBQAAA	Bark beetles (including black turpentine beetle, flathead borer, mountain pine beetle, red turpentine beetle, and western pine beetle)	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. For bark beetles, apply from spring through October. Repeat after new infestations. For Jeffrey needle miner, apply from April through June. For mites, apply after egg hatch. For Nantucket pine tip moth, apply when larval damage is first noticed. For pine needle aphid, apply when wingless forms appear. For pine needle scale, apply when crawlers appear.
INBQAAA	Engraver beetles (including Monterey pine engraver beetle)		
ITAMXYA	Jeffrey needle miner		
ILAAABA	Mites		
INBUDEA	Nantucket pine tip moth		
	Pine needle aphid		
IRAKBRA	Pine needle scale		
/30257AA	Redwood		
INBQAAA ILAAABA	Bark beetles Mites Needle scale	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. For bark beetles, apply when active infestations are present. For mites, apply when eggs hatch. For needle scale, apply when crawlers appear.
/30116AA	Spruce		
IRAZAAA	Aldelgids	1 unit/4-6 in. around trunk at base of tree (50% P/T) 007946-00001	Injection treatment. Apply from May to June.

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Ornamental Plants and Forest Trees)		
/31003FA	Houseplants		
		Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Ornamental Flowering Plants for use information.	
	AERIAL AND TANK MIX APPLICATIONS		
9001500 AAAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cole Crops, Corn, Melons, Peppers, Sorghum, Strawberry TERRESTRIAL NONFOOD CROP (Ornamental Plants and Forest Trees) Christmas Tree Plantation	
9900300 AAAAAAA	Tank Mix		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Corn	

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

Listing of Registered Pesticide Products by Formulation

&100.5002 0.5 lb/gal formulation intermediate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate
(057901)
003125-00343

&225.0002 25% formulation intermediate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
003125-00155

&250.0002 50% formulation intermediate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
003125-00099*
*jacket currently unavailable for review

&250.0005 50% pelleted/tableted
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
007946-00001

&100.2512 0.25 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate
(057901)
000413-00080

&100.4812 0.48 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
005719-00065

&100.5012 0.5 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
003125-00082

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate
(057901)
000070-00239 003125-00165 003125-00274

&101.0012 1 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
001386-00487

&102.0012 2 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
000004-00255* 000070-00241 002749-00198 003125-00111
003125-00133
*jacket currently unavailable for review

(003125-00111) CA750004* CA790064 CA790197 CA790215
CA800184 CA820103 CA820104 FL780011
ID770006 ID770014 ID770017 ID780001

Listing of Registered Pesticide Products by Formulation (continued)

2 lb/gal emulsifiable concentrate (continued)

ID790017 KS800010 NM790025 NM810001*
NV770014 OH800001 OR770019 OR770067
OR790014 OR790024 OR790067* OR800070
OR800071* OR800079 TX780033 TX800024
UT760001 UT770012 UT790006 WA770014
WA770018 WA770058 WA790008 WA790013
WA790058 WA800069 WA800077 WA850003*

*jacket currently unavailable for review

&104.0012 4 lb/gal emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
003125-00312

&202.0012 2% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
001266-00088 011474-00021

&202.4512 2.45% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
007401-00142

&202.5012 2.5% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
007401-00142

&205.0012 5% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus methoxychlor, technical (034001)
007401-00057* 007401-00134

*jacket currently unavailable for review

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol (010501) plus carbaryl (056801)
000239-00741

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
011037-00003

Listing of Registered Pesticide Products by Formulation (continued)

5% emulsifiable concentrate (continued)

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001) plus carbaryl (056801)
005719-00045*
*jacket currently unavailable for review

&205.6012 5.6% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
000557-01771* 007001-00306 007001-00309 002217-00556
007401-00064 007764-00040
*jacket currently unavailable for review

&206.0012 6% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
000802-00488 000869-00102 003442-00832* 007401-00420
007401-00421 007401-00423 033955-00552
*jacket currently unavailable for review

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol (010501) plus methoxychlor, technical (034001)
000072-00157 000572-00208 000904-00160* 002125-00048
005887-00056* 006720-00062 008590-00309* 053127-00026*
*jacket currently unavailable for review

S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol (010501) plus carbaryl (056801)
042057-00082

&206.2512 6.25% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), methoxychlor, technical (034001) plus 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001)
007393-00041

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

Listing of Registered Pesticide Products by Formulation (continued)

&207.5012 7.5% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*-phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001)
008278-10218

&211.7412 11.74% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*-phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001)
000192-00099

&213.5012 13.5% emulsifiable concentrate
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702)
000779-00070 000904-00140 002217-00469*
*jacket currently unavailable for review

&100.5015 0.5 lb/gal soluble concentrate/liquid
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
009404-00040

&205.6015 5.6% soluble concentrate/liquid
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
003442-00868

&206.0015 6% soluble concentrate/liquid
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate (057901)
010370-00173

&200.2519 0.25% pressurized liquid
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702), methoxychlor, technical (034001) plus folpet (081601)
007401-00182

&200.4019 0.4% pressurized liquid
S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate (058702) plus 2,4-dinitro-6-octyl*phenyl crotonate 2,6-dinitro-4-octyl*-phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl (036001)
000192-00098

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

Listing of Registered Pesticide Products by Formulation (continued)

9999999 State Label Registrations

AZ Reg. No.
010163-06397

CA Reg. No.
000909-04695 008278-09248 008278-09271 008278-10218

FL Reg. No.
000829-06775

HI Reg. No.
037643-08563

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S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
010501	dicofol	1,1-bis(chlorophenyl)-2,2,2-trichloroethanol
056801	carbaryl	--
090601	carbofuran	--
057901	trichlorfon (ISO)	dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate
036001	dinocap (ISO)	2,4-dinitro-6-octyl*-phenyl crotonate 2,6-dinitro-4-octyl*-phenyl crotonate nitrooctylphenols (principally dinitro) *a mixture of 1-methylheptyl, 1-ethylhexyl and 1-propylpentyl
081601	folpet	--
034001	methoxychlor	methoxychlor, technical

-- Use Common Name

S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
090601	carbofuran	--

-- Use Common Name

IV. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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V. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE** **ACTIVE INGREDIENT**

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Req. No.____________________ Date ____________________

Guidance Document for ____________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: __________________ ______________________________
(Typed)

EPA Form 8570-27